Embedded Counselling in Student Mental Health:

Development of a Feasibility Trial

Emma Broglia

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Overview

This document contains the appendix that corresponds to Volume I of the thesis entitled: Embedded Counselling in Student Mental Health: Development of a Feasibility Trial.

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Appendix A1

Last accepted version of an article published in Clinical Psychology and Psychotherapy

The Counseling Centre Assessment of Psychological Symptoms (CCAPS-62): Acceptance, feasibility, and initial psychometric properties in a UK student population

Emma Broglia
Abigail Millings
Michael Barkham
University of Sheffield (UK)

Key practitioner message

- University students attending counselling in the UK demonstrate clinical severity for academic distress, depression, anxiety and social anxiety
- Compared to university students in the US, UK students present with higher clinical severity on all contextual measures of student psychological distress
- It is advantageous for university counselling services to administer a student-specific clinical measure over measures intended for the general clinical population
- CCAPS-62 is an acceptable, feasible and psychometrically valid measure of student psychological distress which can be used in the UK without revision
- It is important for university counselling services to continue to provide support from therapists that are trained and experienced in the university context over services intended for the general clinical population

Key words
Academic distress, Anxiety, Assessment, Counselling, Depression, Feasibility,

Abstract

Background: The burden and severity of student mental health continues to increase in parallel with increasing financial pressures on students and services alike. There is a need for a student-specific measure of distress that acknowledges their unique context. This study examined the feasibility, acceptance, and initial psychometric properties of a US measure, the Counseling Centre Assessment of Psychological Symptoms (CCAPS), in a UK student sample.

Methods: A sample of 294 UK help-seeking students from two universities completed the CCAPS-62 and CORE-10 as a comparator. The factor solution and reliability of the CCAPS-62 was examined. Correlations and clinical boundaries were determined between the CCAPS-62 subscales and CORE-10, and comparisons were made with US published norms.

Results: The CCAPS-62 demonstrated a strong factor solution that matched the intended subscales. All subscales had good reliability and correlated significantly with the CORE-10. The agreement on caseness between the two measures was 92.8% with 86.3% reaching clinical threshold on both the CCAPS-62 and CORE-10. Severity was most noticeable for academic distress, depression, anxiety and social anxiety. Compared to US data, UK students showed higher clinical severity for all psychological symptoms.

Conclusions: The CCAPS-62 is a reliable and psychometrically valid assessment measure to use with UK students without revision. The overall distress indicated is similar to that of the CORE-10 but the individual subscales are more informative of specific student concerns. Overall levels for UK students appear higher than US students. Potential benefits of administering a student focused assessment measure in student counselling services are discussed.

Introduction

The increased demand of student mental health has become a global phenomenon and has reached parliamentary debate in the UK. UK initiatives have widened university participation such that students no longer represent a privileged group of society (Sarmento, 2015). Through this growing attendance, students are approaching counselling services at an overall higher demand and with more complex mental health needs (Holm-Hadulla & Koutsoukou-Argyraki, 2015). For example, whilst depression and anxiety are still the most common mental health concerns in students, recent reports have demonstrated a rise in student-specific concerns such as academic distress, substance misuse, family upset, and financial burden (Doerr et al., 2015; Murray, McKenzie, Murray, & Richelieu, 2015). However, inconsistencies in service data have made it difficult to illustrate recent trends in the UK and consequently services have struggled to access resources to support growing demands. During a time of significant change, the need for UK data on student mental health is paramount for service development and decision making.

With this increasing financial pressure, counselling services in Higher Education (HE) have been challenged to demonstrate their impact on student well-being and the wider educational institution (Mccarthy, 2016). However, it has been difficult to demonstrate the specific impact on aspects of student mental health when clinical measures have typically been designed for a non-student population. Measures used with samples of UK students include the General Health Questionnaire (GHQ; Goldberg & Williams, 1991 – see Macaskill, 2012), the General Population-Clinical Outcomes in

Routine Evaluation (GP-CORE; Sinclair et al., 2005 – see Cooke et al., 2006), and the 10-item version of the Clinical Outcomes in Routine Evaluation (CORE-10; Barkham et al., 2013 – see Bewick et al., 2010). Whilst it is beneficial to use any clinical measure rather than none, capturing information that is specific to users ensures that services remain responsive. Furthermore, evidence suggests that focusing on student mental health results in more nuanced data capture and finer analysis of treatment outcomes (Rückert, 2015).

In the US, such concerns have led to the development of a clinical instrument specifically for student counselling services – the Counseling Center Assessment of Psychological Symptoms (CCAPS; Locke et al., 2011; McAleavey et al., 2012). The measure has been widely adopted in US colleges but is yet to be validated in the UK, thereby potentially limiting its utility in UK counselling services. The current study aimed to address these issues by evaluating the feasibility and acceptance of CCAPS in a UK student clinical sample, obtaining preliminary psychometric data on the assessment capability of the measure, comparing profiles with US norms, and benchmarking overall distress levels against the CORE-10 (Barkham et al., 2013). The full version of CCAPS comprises 62 items (CCAPS-62), is administered at initial assessment, and comprises eight scales: depression; generalised anxiety; social anxiety; academic distress; eating concerns; family distress; hostility; substance abuse, and an overall distress index (DI) drawing on items from a majority of the scales. As a clinical instrument, CCAPS-62 detects early signs of risk and can demonstrate clinical severity between different student groups. For example, CCAPS data has highlighted the severity of academic distress in students attending university away from their birth country, when compared to students attending a university in the same country (Locklard, Hayes, McAleavey, & Locke, 2012). Evidence has also shown CCAPS to predict later diagnosis of social phobia when used at the initial assessment (McAleavey et al., 2012).

Evaluating the validity of the CCAPS-62 in the UK is particularly important because its utility may vary across different countries, and the presentation of psychological symptoms has been shown to vary in different student samples (Kreß, Sperth, Hofmann, & Holm-Hadulla, 2015; Villacura et al., 2015; Yang, Lin, Zhu, & Liang, 2015). For example, a recent global report found UK students displayed specific risk for separation distress and conflict between family and studies. By contrast, students in Austria, Germany and Sweden displayed specific risk for psychosomatic issues, exam anxiety and personal identity issues (Rückert, 2015). Even reports within the US have demonstrated an increase in major depression, anxiety, financial distress, personality disorders, and suicidality (Prince, 2015). With large variations in symptom severity and presentation across different student groups it is important to understand how the CCAPS-62 functions in a sample of UK students. Furthermore, using CCAPS to capture information on student mental health in the UK will allow comparisons to be made with other student groups and shed light on global trends. The current study aimed to address this need by examining CCAPS data from a sample of students at two Universities who were receiving counselling from their respective University Counselling Service (UCS). Through this comparison, the study aimed to determine (1) the acceptability and feasibility of the CCAPS-64, (2) its reliability and factor structure, (3) comparisons with reported US data, and (4) comparisons between the overall distress index and the CORE-10.

Method

Design and setting

The study adopted a cohort design comprising students attending one of two UK University Counselling Services during the period April to July 2015. One setting was a large university within a city context (approx. 25,500 students) and the other a smaller university in a town-rural setting (approx. 10,500 students). The study received approval from the University Research Ethics Committee at the University of Sheffield prior to any data collection.

Participants

Participants were 294[1] students [59.6% female] accepted for counselling with a mean age 22.2 [min = 18, max = 54, SD = 4.42]. Students were predominately undergraduate (68%) with 13% studying at master degree level, 8% completing postgraduate research such as PhD, and 8% completing 'other' types of degrees. The most common degree subjects included: science (28.2%), social science (19.4%), arts and humanities (18.4%), engineering (14.3%), and nursing/dentistry/medicine (8.8%).

Measures

Counseling Center Assessment of Psychological Symptoms (CCAPS-62)

CCAPS-62 (Locke et al., 2011) is the only clinical instrument designed specifically for services to measure experiences related to the student population. According to the 2015 CCAPS Clinical Guide[2], the clinical utility of CCAPS is most beneficial when CCAPS-62 is administered as an initial assessment. It comprises eight scales: 1) depression (13 items; e.g., *I feel worthless*); 2) generalised anxiety (9 items; e.g., *I have spells of terror or panic*); 3) social anxiety (7 items; e.g., *I feel uncomfortable around people I don't know*); 4) academic distress (5 items; e.g., *It's hard to stay motivated for my classes*); 5) eating concerns (9 items; e.g., *I feel out of control when I eat*); 6) family distress (6 items; e.g., *I wish my family got along better*); 7) hostility (7 items; e.g., *I have difficulty controlling my temper*); and 8) substance abuse (6 items; e.g., *I drink alcohol frequently*). Items refer to the previous two weeks and are scored on a 5-point Likert scale (0 = *'not at all like me'*; 4 = *'extremely like me'*), whereby higher scores indicate higher symptom severity. In addition, CCAPS-62 yields a distress index (DI) that comprises 19 items drawn from all the scales except eating concerns and family distress. As well as providing a measure of overall distress, the CCAPS DI can be used to determine whether a client meets clinical criteria with a score of ≥ 1.2 indicating clinical caseness.

Within each subscale are two clinical thresholds, termed *low clinical* (LC) and *elevated clinical* (EC), which detail clinical risk on discrete symptoms and may be used to facilitate clinical judgement. These thresholds, along with the clinical utility of the CCAPS-62, have been established from a large normative sample (approx. 250,000) of students receiving therapeutic support. The sample predominately consists of students from the

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[1]Site 1 contributed data from 215 students [59.9 percent female] mean age 21.6 [min = 18, max = 48, SD = 3.38]. Site 2 contributed data from 79 students [58.2 percent female] mean age 24.2 [min = 19, max = 54, SD = 5.88].

[2] Center for Collegiate Mental Health (2015). *CCAPS User Manual.* University Park, PA.

USA who have contributed to the dataset over several years. As a clinical instrument, the CCAPS-62 has been shown to be sensitive to change and possess good test-retest reliability in clinical student samples (McAleavey et al., 2012).

Clinical Outcomes in Routine Evaluation (CORE-10)

The Clinical Outcomes in Routine Evaluation-Outcome Measure (CORE-OM; (M Barkham et al., 2001) has been used extensively in primary care services in the UK for over a decade to provide measures of psychological functioning (Barkham, Culverwell, Spindler, & Twigg, 2005; Evans et al., 2000; Mellor-clark, Connell, & Cummins, 2001). The shortened 10-item version (CORE-10; Barkham et al., 2013) has also been validated against CORE-OM, has been shown to be sensitive to change, and provides a measure of general psychological functioning. Items refer to the previous week and are scored on a 5-point Likert scale (0 = *'not at all'*; 4 = *'most or all of the time'*), with higher scores indicating higher symptom severity.

The CORE-10 total provides a measure of overall psychological functioning that may be derived by calculating the mean (rather than the sum) of all items. This version of calculating the CORE-10 total has been used in previous research and does not impact on its psychometric properties. Furthermore, to permit clinical comparisons with literature using the CORE-10 total as the sum of items, the comparative CORE-10 total can be converted by multiplying the CORE-10 mean by 10. As well as providing a measure of overall psychological functioning, the CORE-10 total can be used to determine whether a client meets clinical criteria. A score of ≥ 1.1 (equivalent to 11/40 on CORE-OM) indicates that a client meets clinical caseness.

Procedure

Use of CCAPS-62 at initial assessment was standard practice at both participating sites and both sites had previously used CORE in one of its formats. Any newly registered student, approved for counselling between April-July 2015, was eligible to participate. An opt-out procedure was used to allow students to withdraw their data from planned analysis. A study guide was developed and shared with staff to encourage standardisation and allocate order of administration.

Posters and information leaflets were displayed in the waiting rooms and raised by staff administering the electronic forms, to ensure that clients were informed and had the opportunity to opt-out. Any clients who elected not to participate (and therefore did not complete the additional CORE-10 form) were excluded from the dataset.

Analytic strategy

All analyses were performed in SPSS statistics package (version 21). Factor Analysis was used to explore the factor structure of CCAPS-62 when applied in the UK. Due to the potential differences in the kinds of distress experienced in student populations in different countries, we did not seek to simply replicate the factor structure previously obtained in US samples. We therefore used Exploratory Factor Analysis (EFA) rather than Confirmatory Factor Analysis (CFA) to allow items to freely vary and permit the underlying constructs in the UK to be different to those found in the US.

There are many judgements to be made in EFA and it is common to explore alternative methods. For the purpose of the current study, the Principle Axis Factor (PAF) extraction method was employed with direct oblimin rotation to examine covariation between the 62 items. PAF and Maximum Likelihood (ML) extraction methods have been deemed relevant for exploring counseling psychology measures (Kahn, 2006) and both extractions were used separately to explore the stability of the factor solution. Whilst both methods yielded similar factors, we report PAF because it is more robust in scenarios where multivariate normal distribution has been violated (Costello & Osborne, 2005; Fabrigar, Wegener, MacCallum, & Strahan, 1999). Direct oblimin rotation, as an oblique rotation method, was used over orthogonal rotation methods because items and factors were anticipated to correlate. Furthermore, alternative oblique rotation methods were explored and yielded the same factor solution.

Reliability analysis was used to explore each CCAPS subscale and compare against published US data. Further comparisons were made between UK and US CCAPS subscale means; to explore differences in symptom severity. Clinical severity was also explored within the UK sample to determine the percentages of students that met low-clinical and elevated-clinical caseness. As measures of overall psychological functioning, the clinical cut-offs of CORE-10 total and CCAPS DI were used to group the sample into 'non-clinical' and 'clinical' to explore potential discrepancies in clinical criteria. Similarities between CORE-10 and CCAPS were also explored with correlations to determine the strength of relationships between CORE-10 and each CCAPS subscale.

Results

Acceptability and feasibility

Completion of measures

Across both UCSs, 401 students (city UCS = 234, rural UCS = 167) completed the CCAPS-62 and CORE-10 forms at their initial clinical assessment between April and July. Of the 401 students, 107 (city UCS = 19, rural UCS = 88) did not go on to receive counselling and were excluded from analyses. Hence the dataset employed in the analyses comprised 294 students: city UCS = 215; rural UCS = 79. Members of staff administering the forms reported that there were no refusals from students.

Missing items

The overall rate of missing items on the CCAPS-62 in the UK sample was 0.002% (38 missing items / 18,228 data points[3]). At the individual item level, item 41 *"I am concerned that other people do not like me"* was omitted by 4 people (1.4%) while item 30 *"I feel tense"* and item 45 *"I feel irritable"* were omitted by 3 people (1%). A further seven items were omitted by 2 people (0.7%) and are as follows: "I feel disconnected from myself" (item 10); "my thoughts are racing" (item 18); "I feel worthless" (item 20); "I have difficulty controlling my temper" (item 32); "I purge to control my weight" (item 48); and "unwanted images or memories have been distressing me" (item 10 of CORE-10). By comparison, for the CORE-10 the only item omitted was item 10 *"unwanted images or memories have been distressing me"* by 2 people (0.7%). On the CCAPS-62 there was no

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[3]CCAPS-62 items for 294 individuals

evidence of fatigue effects as the relationship between item number and the number of missing items was not significant (r = 0.034, *p* = 0.80). The substance abuse scale was the only CCAPS-62 scale with complete data, even though family distress and academic distress contain the same number of items.

Average time taken to complete the forms

As part of routine practice, students arrived 10 minutes before their appointment to complete CCAPS-62. Additional items from CORE-10 were also completed within the allocated time and there were no reports of students requiring >10 minutes to complete both forms.

Ease of scoring

Both UCSs electronically administered CCAPS on computer tablets that wirelessly connected to a secure computer system. Therefore, the computer system automatically scored CCAPS and created a summary report, which was viewable by therapists before meeting with clients. Alongside CCAPS, a CORE-10 from was created on the computer system and used for data collection purposes only; therapists were not required to review CORE-10 results before meeting with clients.

Percentage of students scoring maximum scores on each scale

Potential ceiling effects were explored by calculating the percentage of students who obtained maximum scores on any scale. Maximum scores were found in 4.8% (n = 14) of students experiencing academic distress, and in 0.7% (n = 2) of students with eating concerns. Students did not obtain maximum scores on the remaining scales.

Psychometric properties of CCAPS-62

Exploratory Factor Analysis (EFA)

Sixty-one of the 62 items correlated with at least one other item at 0.3 and above, demonstrating reasonable factorability. The Kaiser-Meyer-Olkin measure verified sampling adequacy (KMO = 0.86) and the Bartlett's test of sphericity was significant (χ^2 (171) = 2778.15, *p* < 0.001), suggesting that correlations between items were sufficient for analysis. As shown in Table 2, the commonalities between items were above .40 and the factors remained clear, even at a more conservative factor loading of .65 (40% overlapping variance), thereby confirming common variance with other items (Field, Miles, & Field, 2012; Tabachnick & Fidell, 2007).

The scree plot displayed an inflection at Factor 8, which was also the last substantial drop in Eigenvalues (see Appendix 1). Both criteria suggested retaining 8 factors which collectively explained 54% of the variance (Kahn, 2006). Table 1 displays the factor loadings from the pattern and structure matrices (before/after item rotation) which include: depression (4 items); substance abuse (6 items); eating concerns (8 items); GAD (7 items); family distress (6 items); social anxiety (7 items); hostility (7 items); and academic distress (5 items). The pattern and structure matrices were typically consistent and items within each extracted factor were congruent with the intended CCAPS subscales.

[Insert table 1 here]

Internal reliability

Reliability analyses on the CCAPS-62 data revealed Cronbach alpha values for the eight subscales and the Distress Index to range from 0.81 to 0.89 (see Table 2), indicating good internal reliability for all subscales. Of note, with the exception of substance abuse, alpha values were slightly lower than values derived from US student samples.

[Insert table 2 here]

Comparisons between CCAPS-62 and CORE-10

Correlational analysis

As data were normally distributed, Pearson's correlation was used to explore the strength of the relationship between CORE-10 and each of the CCAPS-62 sub-scales. All CCAPS-62 subscales correlated significantly with the CORE-10: depression ($r = .75$, $p < .001$); general anxiety ($r = .65$, $p < .001$); social anxiety ($r = .34$, $p < .001$): academic distress ($r = .44$, $p < .001$); eating concerns ($r = .31$, $p < .001$); family distress ($r = .30$, $p < .001$); hostility ($r = .42$, $p < .001$); substance misuse ($r = .14$, $p = .034$); and distress ($r = .77$, $p < .001$). The strongest correlation occurred between the CORE-10 total and CCAPS DI followed by depression and GAD. The weakest correlation was between CORE-10 and family distress followed by eating concerns, social anxiety, hostility and academic distress.

Clinical Cut-off

Comparisons were made between the CCAPS DI and the CORE-10 as measures of overall psychological functioning. The clinical cut-off on each measure was used to group the sample into 'non-clinical' and 'clinical' to determine the extent of agreement and discrepancies in clinical caseness or not caseness across each measure. A total of 85.3% students met the clinical threshold on CCAPS DI (a score ≥ 1.21) while 90.1% of students met the clinical threshold on the CORE-10 (a score ≥ 1.1). The scatter diagram in Figure 1 demonstrates that 92.8% of students were classified in the same way across CCAPS DI and CORE-10, with 86.3% of students categorized as clinical and 6.5% non-clinical on both measures. The remaining 7.2% discrepancy resulted in students meeting clinical criteria on one measure but not the other for each measure.

Further comparisons utilised thresholds from the US norms that distinguished between non-clinical, low-clinical and elevated-clinical groups on the CCAPS-62. This revealed that the largest elevated-clinical group existed for depression, followed by academic distress, GAD and social anxiety (see Figure 2). The highest percentage of students who met non-clinical criteria existed for eating concerns, substance abuse, and hostility.

Profiles of UK sample and comparisons with US norms

Finally, following a scope of initial psychometric properties of the CCAPS, we investigated mean scores on the subscales as compared with published US data from various sources. Table 3 reports the means and their rank order together with SDs for the CCAPS-62 subscales together with comparisons with published US norms. The data shows the highest scores are for academic distress, depression, GAD and social anxiety. These levels

and rankings are also presented in the box and whisker plot in Figure 3. Inspection of Figure 3 shows two distinct symptom clusters for the eight subscales. One cluster comprises academic distress, depression, GAD and social anxiety, while a second cluster comprises eating concerns, family distress, hostility and substance abuse. In a direct comparison between the Distress Index and CORE-10, students scored significantly higher on the Distress Index; t(293) = 51.944, $p < 0.001$).

[Insert table 3 here]

Discussion

The current study is the first examination of the acceptability and feasibility of implementing the CCAPS-62 in a UK clinical student population as well as determining its structure and reliability. We sought to benchmark it against a brief standard measure of psychological distress using the CORE-10 and to make initial comparisons with US normative data. We applied a range of indices of acceptability and feasibility and found them all to indicate the overall acceptability and feasibility of adopting the CCAPS-62 in a student population. No student refused to complete the CCAPS when it was presented as standard procedure. Missing items were virtually negligible and there was no evidence of fatigue effects. Two of the subscales showed a ceiling effect but the total number of students scoring 4.00 on any subscale was 16, of which 14 of these obtained the maximum score on Academic Distress. Given that this full version of the CCAPS is recommended for use as an initial assessment tool, the inclusion of a scale tapping academic distress as a unique experience of students is sufficient to outweigh this low rate of maximum scoring.

We anticipated differences in the factor structure of CCAPS in the UK compared the US because of the known differences in symptom expression across different countries. However, strikingly, the factor structure mimicked the intended subscales and displayed a robust factor solution across two methods. This suggests that the CCAPS-62 subscales established with US samples are appropriate for use in the UK without alteration. This finding was consolidated when individual subscales were explored and were shown to be highly reliable. Although alpha levels for all subscales in the UK sample, except for substance abuse, were lower than in the US data, all values fell within the range of .8, a value also obtained for the CORE-10. Given that the number of items in the CCAPS scales range from 5 to 19, the relatively tight range of alpha values is reassuring. This finding provides confidence in the discrete value to practitioners of each of the eight subscales.

In terms of comparisons between the CCAPS-62 and CORE-10, there might appear to be a clear choice between capturing a broad assessment of presenting issues (CCAPS) and a brief overall distress score (CORE). However, the Distress Index (DI) appeared to largely mimic the CORE-10 as evidenced by the high correlation but more importantly by the high rate of agreement (92.8%) in determining casesness or not. Within this 92.8% of cases, 86.3% of our sample reached clinical threshold on CCAPS DI compared to only 73% of a US student sample (Duszak, 2014). Hence, CCAPS comprises reliable subscales that do not evidence any fatigue effects due to its length but can also yield an overall index of psychological distress that is more than 90 per cent accurate in determining caseness or not when compared with a UK-derived outcome measure.

In terms of the eight subscales and their scores in the present sample, two clear clusters or groupings appeared with higher scores (severity) being achieved on Academic

Distress, Depression, GAD, and Social Anxiety, while lower scores were obtained on Eating Concerns, Family Distress, Hostility, and Substance Abuse. These two groupings appear intuitively meaningful in that the former comprises three prevalent conditions reported in primary care settings with the associated impact on academic performance (or visa versa). As such, they are consistent with findings reported by Connell, Barkham, Mellor-Clark and (2008) using the full version of the CORE-OM (Evans et al., 2002) and the Therapy Assessment Form (Mellor-Clark & Barkham, 2006) in which the highest presenting problems in a sample of students were anxiety, interpersonal problems, depression, self-esteem, and academic problems. The latter grouping reflects more complex presenting conditions that might be viewed as requiring secondary or more specialist interventions.

Comparisons were made between UK and US symptom severity to elucidate recent trends on UK mental ill health. Strikingly, UK students were elevated on all CCAPS subscales compared to US (Martin, Hess, Ain, Nelson, & Locke, 2012; McAleavey et al., 2012;Martin, Hess, Ain, Nelson, & Locke, 2012; McAleavey et al., 2012). This was most noticeable for the first grouping of presenting problems (i.e., depression, academic distress, GAD and social anxiety). Given that the overall indices of psychological distress – the DI and CORE-10 – have a high level of agreement in terms of caseness or not, then it is reasonable to take the UK scores as valid responses to the CCAPS. Hence it would appear that in the present sample at least, UK students scored consistently higher when compared against the US norms. However, although symptoms were more severe in UK students than US, this was less noticeable for eating concerns, family distress, hostility, and substance abuse. These differences may suggest that UK students approach services at higher severity levels than US students and reflect differences in help-seeking behaviour between the two countries.

These differences also reflect the severity of academic distress experienced by help-seeking students in the UK, which highlights the need for practitioners in student counselling services to be experienced in the student context. In effect, student counselling services need to be viewed as a specialist service embedded within university settings rather than potentially being outsourced. For example, while it is highly likely that services such as the UK Improving Access to Psychological Therapies (IAPT) initiative could provide supportive interventions to help-seeking students, it is unlikely that they would have the implicit knowledge base of university routine and scheduling that defines the lives of students. In addition, in many ways students present as a unique population in terms of their age, transient living style, limited tenure (i.e., usually 3 years), reliance on digital technology, and financial constraints. Hence, it can be argued that students require highly developed but flexible in-house services that blend a knowledge of university demands but also utilise the increasing array of digital devices and technologies in order to reach out to students.

Taken together, the initial findings regarding the CCAPS-62 suggest it to be a valid measure of student psychological distress for use with UK students. In addition, they also yield information about probable elevated distress levels for UK students compared with US students and also show the highest relative subscale score to relate to academic distress. The ability of the measure to highlight specific student concerns strongly supports its use in this population.

Conclusions

The current study aimed to provide the initial step in determining the acceptability, feasibility, and potential of the CCAPS-62 as a measure of distress in UK help-seeking students. Our findings illustrate clinical severity in UK help-seeking students beyond that of students in the US. Importantly, the extent of severity was not reflected in the generic measure of general psychological distress, that is the CCAPS Distress Index when compared with the CORE-10. However, specific subscales and in particular Academic Distress, were distinctly elevated. These findings highlight the benefit of measuring components that are specific to students rather than necessarily relying solely on overall measures of distress, which yielded very similar results. Taken together, our findings provide initial validation for use of CCAPS-62 in the UK without requiring revision.

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Acknowledgments

Appendix A2

Published version of an article in Pilot and Feasibility Studies

STUDY PROTOCOL   **Open Access**

Comparing counselling alone versus counselling supplemented with guided use of a well-being app for university students experiencing anxiety or depression (CASELOAD): protocol for a feasibility trial

Emma Broglia[1]*, Abigail Millings[1] and Michael Barkham[1,2]

Abstract

Background: University counselling services face a unique challenge to offer short-term therapeutic support to students presenting with complex mental health needs and in a setting which suits the academic timetable. The recent availability of mobile phone applications (apps) offers an opportunity to supplement face-to-face therapy and has the potential to reach a wider audience, maintain engagement between therapy sessions, and enhance therapeutic outcomes. The present study, entitled Counselling plus Apps for Students Experiencing Levels of Anxiety or Depression (CASELOAD), aims to explore the feasibility of supplementing counselling with guided use of a well-being app.

Methods/Design: Forty help-seeking university students (aged 18 years and over) with symptoms of moderate anxiety or depression will be recruited from a University Counselling Service (UCS) in the United Kingdom (UK). Participants will be recruited via counsellors who provide the initial clinical assessment and who determine treatment allocation to one of two treatments on the basis of client-treatment fit. The two conditions comprise (1) counselling alone (treatment as usual/TAU) or (2) counselling supplemented with guided use of a well-being app (enhanced intervention). Trained counsellors will deliver up to six counselling sessions in each treatment arm across a 6-month period, and the session frequency will be decided by client-counsellor discussion. Assessments will occur at baseline, every counselling session, post-intervention (3 months after consent) and follow-up (6 months after consent). Assessments will include clinical measures of anxiety, depression, psychological functioning, specific mental health concerns (e.g. academic distress and substance misuse), resilience and therapeutic alliance. The usage, acceptability, feasibility and potential implications of combining counselling with guided use of the well-being app will be assessed through audio recordings of counselling sessions, telephone interviews with participants, focus groups with counsellors and counsellor notes.

Discussion: This study will inform the design of a randomised pilot trial and a definitive trial which aim to improve therapy engagement, reduce dropout and enhance clinical outcomes of student counselling.

Trial registration: ISRCTN55102899

Keywords: Student mental health, Anxiety, Depression, Counselling, Well-being app, Behaviour monitoring, Augmented therapy, Feasibility, Acceptability

* Correspondence: elbroglia1@sheffield.ac.uk
[1]Department of Psychology, University of Sheffield, Sheffield S10 2TN, UK
Full list of author information is available at the end of the article

Background

There is limited evidence demonstrating the effectiveness of counselling services in higher education (HE), and recent government initiatives have negatively impacted on student services. These changes have been particularly noticeable in the United Kingdom (UK), since new policies have raised tuition fees and widened access to university without financially supporting service growth [1]. As a result, there is more pressure on university counselling services (UCSs) to demonstrate effectiveness and explore innovative solutions to continue to offer high-quality support with less resource in a sustainable way [2]. This is particularly challenging for student counselling services because they support a unique population with mental health needs that require counsellors/therapists who are trained and experienced in the academic context. For example, students require support that fits within the academic calendar and around periods of time when students are away from campus. Technology-assisted therapy provides a promising solution to support student counselling, but the feasibility and effectiveness of doing so are unknown [3, 4]. The current study aims to address these challenges by exploring the feasibility of supplementing face-to-face counselling with guided use of a well-being app for university students experiencing anxiety or depression.

University counselling services (UCS) in the UK

UCSs are frequently evolving to address student demands and this has been widely accepted as a necessity [5, 6]. For example, a recent qualitative study summarised the changes experienced in a UK UCS [7]. These included the following prominent themes: (1) counsellors are being encouraged to work more flexibly by catering the number and frequency of therapy sessions to best suit their clients' needs; (2) UCSs are offering more online support (e.g. online self-help) to manage growing demands with limited financial resources; (3) counsellors' workloads are increasing to maintain high standards and meet growing demands in the absence of service expansion; (4) UCSs continue to be pressured to demonstrate effectiveness; and (5) there are concerns that UCSs may not be collecting the right type of data, not using the available data, or missing data after counselling. Furthermore, a recent investigation of the usage and acceptability of therapeutic technology in student counselling revealed that many services are interested in knowing how contemporary therapeutic technology, such as mobile apps, can be used in student services and the potential implications of doing so (Broglia, Millings, & Barkham: The burden of student mental health on embedded counselling services in UK Higher and Further Education institutions, submitted). Taken together, these findings demonstrate how UK UCSs are embracing change and exploring innovative solutions to address recent trends in student mental health.

Feedback in therapy

In conjunction with finding new innovative solutions to address changes in UCSs, it is also important to explore whether existing methods can be enhanced to improve outcomes. One such method involves therapists providing feedback to clients about their responses on a clinical outcome measure in order to help clients acknowledge their progress or to raise discussion about adapting treatment. This method of integrating feedback into therapy has been widely explored and its impact on clinical outcomes have been summarised in a recent scoping review [8]. For example, compared to clients who received no feedback, clients who had feedback from clinical measures discussed in therapy (i) improved to a greater degree, (ii) demonstrated improvements sooner, (iii) required fewer therapy sessions, (iv) were less likely to drop-out of therapy and (v) maintained improvements at 6- and 12-month follow-ups. However, by contrast, a recent meta-analysis of 17 clinical trials found no significant differences between feedback and no-feedback groups on symptom outcomes [9]. Whilst there are mixed findings on the potential benefits of using feedback in therapy, the meta-analysis also concluded that the clinical trials exploring feedback in therapy exhibit strong bias and weak methodology.

Taken together, these mixed findings highlight the need for more rigorously designed clinical trials to explore the potential benefits of discussing feedback in therapy. Additionally, there is a need to understand the potential of augmenting therapy using technology, and monitoring feedback is a logical area in which to do this [10], given the ease with which mobile devices enable individuals to track various aspects of self-related data. Aside from the use of mobile technology to increase access to and uptake of psychological support, research demonstrates that therapeutic technologies can be cost-effective, acceptable, and show the potential to enhance the therapeutic process [11–13]. Therefore, whilst positive findings regarding feedback relate to clinical outcome, the current study aims to apply the feedback model to discussing client thoughts, behaviours, emotions and activities monitored daily on a well-being app.

The current study

The primary aim of the current study, offering face-to-face counselling, is to demonstrate whether discussion and guided use of a well-being app can be integrated into counselling sessions with university students experiencing anxiety or depression. This feasibility metric will be assessed through evaluation of therapeutic discussion from counselling audio recordings, telephone interviews with participants and a focus group with counsellors. Through this primary aim, the current study will also evaluate feasibility factors related to recruitment, acceptability, intervention delivery and clinical outcome

monitoring. Therefore, the primary feasibility outcomes will comprise (i) recruitment duration to reach target sample size, (ii) client treatment preferences, (iii) acceptability of randomisation, (iv) intervention fidelity, (v) client/counsellor satisfaction and (vi) completion rate of follow-up measures. Secondary aims will explore the preliminary impact (in terms of effectiveness) and potential moderators for a fully powered definitive RCT. Preliminary impact will be assessed by comparing differences in therapeutic alliance between TAU and the enhanced intervention condition, as well as capturing participants' views on the impact counselling has had on their well-being and

ability to cope at university. Potential intervention moderators will include app usage during and between counselling sessions, as well as client characteristics.

Methods/Design
Study design
The feasibility trial utilises a two-arm, parallel non-randomised design comparing counselling alone (TAU) versus counselling supplemented with guided use of a well-being app and discussion of app activities (enhanced intervention) for university students experiencing anxiety or depression. This is displayed in Fig. 1.
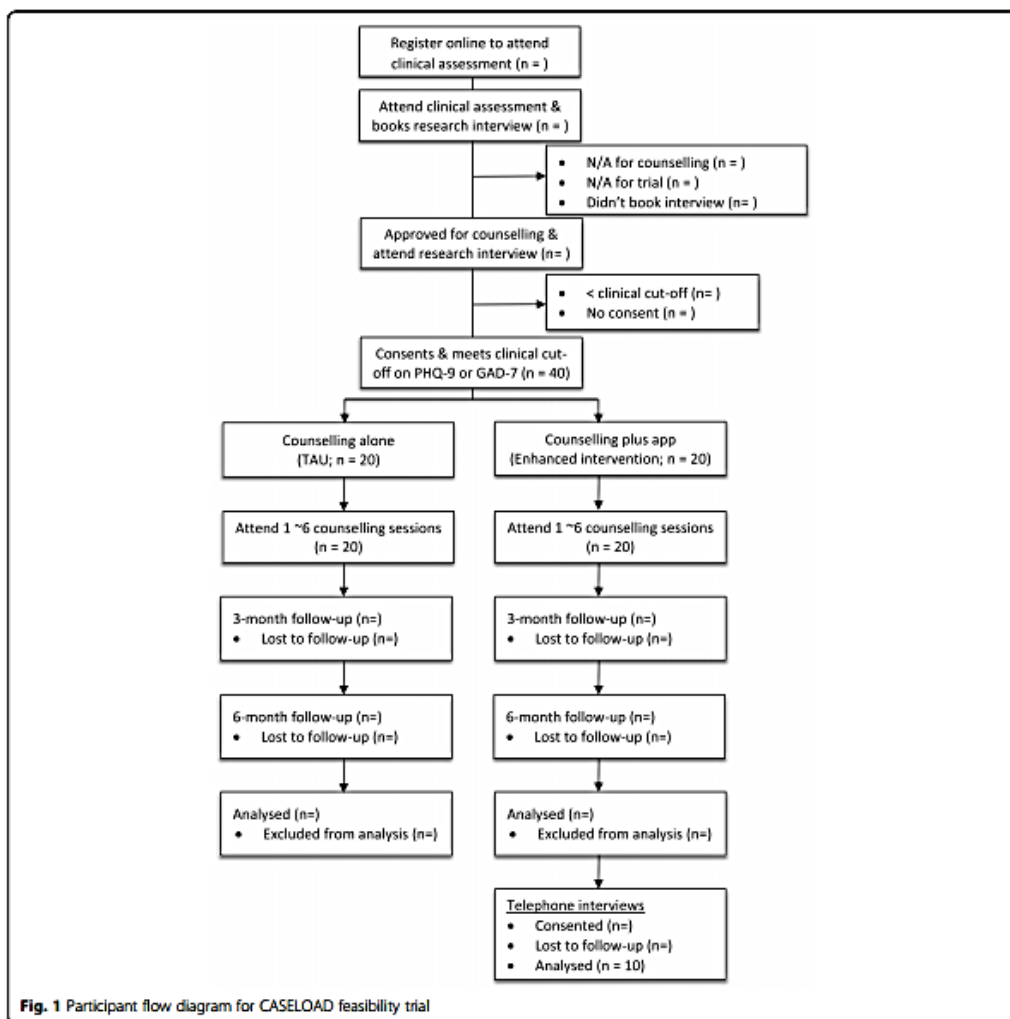
Fig. 1 Participant flow diagram for CASELOAD feasibility trial

The feasibility trial was registered on the BioMed Central ISRCTN registry on 20/06/2016 under the acronym CASELOAD (Counselling plus Apps for Students Experiencing Levels Of Anxiety or Depression).

Ethical approval
This study received ethical approval from the University of Sheffield, Department of Psychology, Research Ethics Committee (REC) on 05/01/2016 (ref: 006171).[1] The research-informed training programme within the current study also received separate ethical approval from the University of Sheffield, Department of Psychology, REC on 17/11/2015 (ref: 006727).

Study setting
The trial will take place at the University of Sheffield UCS which receives approximately 1,300 student referrals annually.[2] The UCS has an ethos of supporting research and embraced the proposed feasibility trial. Extensive joint meetings took place to discuss the trial design and, in particular, to ensure that its implementation is embedded into practice with minimal disruption to the service.

Study population
Participants are 40 help-seeking university students (aged 18 and over) who have been approved for counselling and meet moderate clinical criteria for anxiety (score ≥10 on the Patient Health Questionnaire, PHQ-9—see later section) or depression (score ≥10 on the Generalised Anxiety Disorder Scale, GAD-7—see later section). Inclusion criteria comprise (i) undergraduates (all years), (ii) postgraduates and (iii) international students. Participants will be excluded if they meet any of the following criteria: (i) present with a high risk to self or others, (ii) are currently receiving therapeutic support or (iii) have complex mental health problems beyond anxiety and/or depression.

Recruitment
In line with routine practice, students who approach the counselling service will be assessed by a counsellor to determine their appropriateness for counselling. Students who are approved for counselling (based on clinical judgement) will be provided with a study information booklet and invited to attend a 20-min research interview onsite to determine their eligibility. Leaflets, booklets and posters will also be displayed in the waiting room to raise awareness of the trial and encourage students to volunteer. Students who attend the research interview will be asked to provide written informed consent and will be assessed for eligibility through completion of the PHQ-9 and GAD-7. Eligible participants will be allocated to either the TAU condition or enhanced intervention according to the

clinical judgement of the counsellor that provided the initial assessment.

Allocation
This study is a non-randomised feasibility trial that aims to address the acceptability of randomisation prior to planning a pilot trial in preparation for a future definitive trial. Therefore, allocation will be based on counsellors' clinical judgement of each student's unique situation and primary reason for approaching the service. This will inform the acceptability and feasibility of randomising for the pilot trial. Participant allocation will also depend on whether the assessing counsellor is involved in the trial (based on availability) and whether the counsellor is participating in the provision of the enhanced intervention or TAU condition. Because the enhanced intervention relies on counsellors that are committed and trained to supplement counselling with a well-being app, participants assessed by counsellors in the TAU condition will not have the opportunity to join the enhanced intervention. However, participants assessed by counsellors in the enhanced intervention may be allocated to either condition as determined by their counsellor. Similarly, participants assessed by counsellors providing the enhanced intervention for whom the app is deemed inappropriate (e.g. client presents with inappropriate/excessive technology use or risk negative exposure to online communities for self-harm) will be allocated to TAU.

Considering these design elements, allocation will depend on the following factors: (i) whether the initial clinical assessment is with a counsellor who is part of the trial; (ii) whether the assessing counsellor is allocated to provide the enhanced intervention or TAU condition; (iii) the clinical judgement of the counsellor regarding whether participating in the trial would be appropriate for the client; and (iv) the clinical judgement of the counsellor regarding which intervention would be appropriate for the client. Whilst this allocation procedure is reliant on a counsellor's clinical judgement, it is arguably the most appropriate allocation method for a non-randomised study and it keeps the client's welfare in the forefront. Integrating a well-being app with face-to-face counselling with students experiencing moderate anxiety or depression is a new development with limited understanding of the implications. Therefore, using clinical judgement to inform the allocation will better monitor risk and feasibility metrics which counsellors will document to inform the screening criteria of a future randomised trial.

After the routine clinical assessment, participants will attend a one-to-one research interview (approximately 20 min) to provide written informed consent and determine eligibility before potentially joining the trial. During

the research interview all participants will be informed about both treatment conditions and will be asked their preference (See later section on "Treatment preference"). The preference, as well as associated reasons for preference, will be recorded in the recruitment checklist information. Irrespective of the condition, participants will not be asked to cease using any existing well-being apps, but their use will be noted in the recruitment session and explored in the exit telephone interviews. Whilst the use of existing apps may pose risk of contamination, the enhanced intervention relies on the integration of app activity within counselling and participants in the control condition will not receive guided advice on the well-being apps they may use. In addition, group differences in outcome measures can be compared before/after participants are removed for using additional well-being apps. Combined, this information will be used to inform the recruitment rate, randomisation procedure, allocation procedure and blinding for a fully powered RCT.

Counsellors

All counsellors in the trial are accredited either by the British Association for Counselling and Psychotherapy (BACP) or the UK Council for Psychotherapy (UKCP) and are employed by the UCS. A minimum of 6 counsellors (2 control, 4 intervention) will be assigned to support the trial, both in development and delivery, and will deliver either the enhanced intervention or TAU condition based on their preference. Counsellors will also be trained by a researcher in the details specific to the intervention they are allocated to (see "Training" section below). When entering the trial, counsellors will provide a statement describing their model of practice and specific therapeutic style. The aim of collecting these statements is to improve the reporting quality when describing the therapy available, and to aid development of a clinical manual as an outcome of the feasibility trial.

Counsellors will also be provided with the BACP competency framework [14] for the University and College Counselling (UCC) context together with the most recent service clinical handbook in order to ensure best practice. Whilst these handbooks will be used to reinforce clinical competency throughout the trial, one outcome of the feasibility trial is to refine the clinical frameworks and develop a manualised training programme for delivering the enhanced intervention in a university counselling setting. For the present study, clinical practice will be reinforced throughout the trial with fortnightly team meetings with the head of service, onsite researcher and counselling team. There will also be optional daily drop-in sessions for members of the counselling team to query issues with the onsite researcher.

Measures

The timeframe for administering measures has been summarised in Table 1 and in a Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) diagram in Fig. 2. The clinical outcome measures and primary and secondary feasibility measures have been detailed below.

Clinical outcomes

Clinical Outcomes in Routine Evaluation (CORE-10)
The 10-item Clinical Outcomes in Routine Evaluation outcome measure [15] will be administered at the initial clinical assessment (pre-intervention) and at every counselling session, to measure changes in general psychological functioning. Items refer to the previous week and are scored on a 5-point Likert scale (0 = "not at all"; 4 = "most or all of the time"), whereby higher scores indicate higher symptom severity. CORE-10 is a shortened version of the Clinical Outcomes in Routine Evaluation - Outcome Measure [16] which has been used extensively in mental health services in the UK for over a decade. The 10-item version has been validated against CORE-OM, has been shown to be sensitive to change and can

Table 1 Summary and timeframe of measure administration

Measure	Clinical assessment	Consent session	S1	S2	S3	S4	S5	S6	Last session[a]	3-month follow-up	6-month follow-up
CORE-10	×		×	×	×	×	×	×	×		
CCAPS-62	×										
CCAPS-34			×	×	×	×	×	×	×		
PHQ-9		×								×	×
GAD-7		×								×	×
CD-RISC 10		×								×	×
WAI-12				×							
CSQ-8									×		

[a]This may be any session number beyond session 2 as the number of sessions will vary across clients and will be dependent on client-counsellor agreement

	STUDY PERIOD												
	Enrolment	Allocation	Post-allocation										Close-out
TIMEPOINT	$-t_1$	**0**	t_1	t_2	t_3	t_4	t_5	t_6	t_7	t_8	t_9	t_{10}	t_x
ENROLMENT:													
Clinical assessment	X												
Eligibility screen	X												
Informed consent	X												
Allocation	X												
INTERVENTIONS:													
Counselling alone (TAU)			●———————●										
Counselling plus well-being app (enhanced intervention)			●———————●										
ASSESSMENTS:													
PHQ-9, GAD-7	X	X									X	X	
CD-RISC 10 (resilience)		X									X	X	
CORE-10, CCAPS	X	X	X	X	X	X	X	X					
WAI (therapeutic alliance)				X									
Randomisation acceptability, treatment preference,		X											
Intervention fidelity			X	X	X	X	X	X	X	X			
CSQ-8 (and client satisfaction)									X	X			X

Fig. 2 SPIRIT diagram displaying schedule of enrolment, interventions and assessments of the CASELOAD feasibility trial

be used to determine whether a client meets membership of a clinical population (score ≥11).

Counseling Center Assessment of Psychological Symptoms (CCAPS) CCAPS [17] is a measure developed in the USA specifically for the student college population and will be administered with CORE-10 at the initial clinical assessment (pre-intervention) and every counselling session to measure changes in student-specific mental health concerns. Items refer to the previous 2-week period and are scored on a 5-point Likert scale (0 = "not at all like me"; 4 = "extremely like me"), whereby higher scores indicate higher symptom severity. In addition, because CCAPS was designed for UCSs to measure student mental health, it also monitors changes in the following areas: depression, generalised anxiety, social anxiety, academic distress, eating concerns, hostility, substance abuse, family distress and suicide ideation. Within each construct, CCAPS determines clinical membership (e.g. clinical versus non-clinical) and severity (e.g. low versus elevated clinical severity),

which are detailed in the CCAPS clinical guide. Finally, CCAPS has been validated in UK samples through use in UK UCS and in a recent doctoral research project [18].

Patient Health Questionnaire (PHQ-9) and Generalised Anxiety Disorder scale (GAD-7) The 9-item Patient Health Questionnaire [19] and 7-item Generalised Anxiety Disorder scale [20] will be administered in the research interview, after treatment completion (3-month follow-up), and at follow-up (6-month follow-up), to measure depression and anxiety to determine eligibility. Clients who reach moderate clinical criteria for depression (score ≥10) or anxiety (score ≥10) will be invited into the trial. These measures will also be administered at 3 and 6 months after the consent date to monitor changes in symptoms. Items on PHQ-9 and GAD-7 refer to the last 2 weeks and are scored on a 4-point Likert scale (0 = "not at all"; 3 = "nearly every day") whereby higher scores indicate higher severity. Both measures have been used widely by mental health services to measure depression and is mandatory in the Improving

Access to Psychological Therapies (IAPT) initiative in the National Health Service (NHS). The purpose of using these measures in the current study is to benchmark outcomes against primary care services accessed by the general clinical population in order to allow comparisons between student and non-student clinical populations.

Connor-Davidson Resilience Scale (CD-RISC 10) The 10-item Connor-Davidson Resilience Scale [21] will be administered in the research interview (pre-treatment), after completion of counselling (3-month follow-up), and at follow-up (6-month follow-up) to measure changes in resilience. Items refer to the previous month and are scored on a 5-point Likert scale (0 = "not true at all"; 4 = "true nearly all of the time"), whereby higher scores demonstrate higher resilience. By measuring resilience, the CD-RISC 10 also measures an individual's ability to tolerate change, pressure, personal problems, negative outcomes, painful feelings and illness. The CD-RISC 10 is a short version of the original CD-RISC 25, has good internal consistency (Cronbach alpha .85), has good construct validity (e.g. resilience moderates impact of maltreatment on mental health) and has been demonstrated to have a factor structure which is more stable than CD-RISC 25 [21, 22].

Selection of a well-being app
There are a large variety of smartphone apps that offer tools and support for improving wellbeing via a range of common features. Whilst there are many apps to choose from they are typically based on Cognitive Behavioural Therapy (CBT) and mindfulness to offer tools for (1) tracking daily moods and behaviours, (2) reflecting on diary entries, (3) setting goals, (4) completing exercises to relax and defuse negative emotions and (5) interacting with anonymous online support communities for peer-led support. Some of the most promising well-being apps include Pacifica (http://www.thinkpacifica.com/), Headspace (https://www.headspace.com/) and Buddy App[3]. To aid the decision of selecting a well-being app for the current study, the following criteria were applied: (1) applicable to university students (e.g. providing tools to help manage social anxiety, depression, stress and general aspects of student lifestyle); (2) demonstrates potential to be integrated with face-to-face counselling; (3) available across iOS and Android platforms; (4) offers a range of features overlapping with other well-being apps; and (5) provides a promising free version to permit continued service use after the trial without financial implications.

Based on these criteria, the Pacifica app was selected and evaluated with a volunteer student sample (see next section), before it was implemented in the current feasibility trial. Whilst the app offers a free version with restricted variations of each feature (e.g. only 3 relaxation exercises compared to 8–10), the full version was used in both the evaluation study and current study to allow robust evaluation of all available features representative of other well-being apps. Furthermore, a secondary feasibility outcome will explore the added gain of using the full version compared to the free version. In both studies, a series of annual app subscriptions were purchased and provided to participants as unique gift codes. All payments were subject to the standard fee for public users and no financial incentives or waivers were provided by the Pacifica development team. Whilst the present study utilised a specific app (i.e. Pacifica), our reasoning was that this app was used in the trial as representative of well-designed apps in the field rather than being an evaluation of Pacifica per se.

Evaluation of well-being app (Pacifica)
To aid the training, risk monitoring and intervention delivery of a well-being app in the current study, a preliminary evaluation study was conducted with the well-being app (ethical approval reference: University of Sheffield, Department of Psychology, 006727). The aims of the evaluation study were twofold: (i) to explore students' experiences of using the well-being app to determine features that require additional support and (ii) to explore counsellors' experiences of using the well-being app to understand how various features could compliment counselling. The student sample comprised 20 healthy volunteers (UG and PG) whereas the counsellor sample included members of the counselling team who were already scheduled to engage with the feasibility trial. Students attended a research session to learn about each app feature and were encouraged to use the app daily for 7 days. Students were instructed to use all app features once before selecting 2–3 features to use throughout the week. At the end of the week, students completed an evaluation form, inputted their app data into a spreadsheet and described their overall experience to a researcher in an interview. Based on their feedback and availability, 8 students (UG and PG with positive and negative experiences) attended a focus group to discuss their experiences and suggestions for improving the app.

The counsellor sample comprised 6 counsellors from the UCS who were scheduled to deliver the enhanced intervention condition of the feasibility trial. After attending a one-to-one research session to learn about each app feature, counsellors were instructed to use the app daily for 7 days. During this time, counsellors were advised to use all app features and to consider (1) clients who may benefit from using each feature and (2) how the app could be integrated between and within counselling sessions. At the end of the week, counsellors attended a focus group to discuss the feasibility of clients

using the app alongside counselling and whether it would be feasible to review app activity during counselling sessions. Feedback from student and counsellor groups shaped the enhanced intervention and refined staff training for the current feasibility trial.

Training

Prior to commencement of the trial, all participating counsellors will attend a one-to-one training session with a researcher to address the following: (1) knowledge of the trial research process; (2) language use for describing the trial to students; (3) counsellor expectations; and (4) areas of concern. Training sessions with counsellors in the enhanced intervention condition will additionally cover (1) willingness to audio record therapy sessions, (2) client consent to audio record therapy sessions, (3) therapeutic rationale for various app features and (4) research rationale for supplementing counselling with guided use of a well-being app. Following this, counsellors will be invited to a condition-specific training session to reduce discussion between counsellors and ensure that the enhanced intervention is delivered by counsellors who are engaged and committed to using a well-being app alongside therapy. Therefore, training with counsellors in the TAU group will only address research requirements (e.g. recruitment) and will focus on the research rationale for using an active control group and language use for recruitment.

To encourage integration of the app during counselling sessions and encourage discussion of client app activity, counsellors in the enhanced intervention will be provided with computer tablets to use during therapy sessions to review and discuss app features with clients. During training, counsellors will practice using the tablet to navigate through various app features and a range of role play exercises will be used to mimic different therapy scenarios. The tablet will also be used to audio record therapy sessions and counsellors will practice using the recording feature during training. The training session will be guided with a manual which will provide examples of how to address various scenarios as well as brief scripts to prompt counsellors during training. Script examples include the following: inviting students to book a research interview; describing the intervention in the first counselling session; confirming participant's involvement in the study at the first counselling session; confirming permission to audio record; commencing app discussion during therapy sessions; reviewing app activity; inviting participants to use the computer tablet; and supporting participants who decide to withdraw from the trial. Counsellors will also be encouraged to make notes in their training manual to cater the examples to suit their therapeutic style.

These practical sessions aim to ensure that counsellors are confident with the technology requirements and feel at ease using the app in a therapeutic context. Therefore, counsellors will be put into pairs to practice each example and will alternate between client and counsellor roles. More specifically, when counsellors are in the role of a hypothetical client they will be asked to mimic potentially challenging behaviours they have previously experienced during sessions with their own clients. These exercises aim to challenge counsellors before they start using the app with clients. Counsellors will also have the opportunity to role-play examples with the onsite researcher throughout the trial to build confidence and refresh training. At the end of the training session, counsellors will complete a feedback form detailing their confidence in executing technical, administrative and therapeutic requirements of the trial. This information, combined with feedback from the focus group at the end of the trial, will be used to improve the manualised training for the definitive trial.

Technology acceptability

Despite the prevalence of technology being integrated into physical and mental health interventions, staff acceptability has been an ongoing issue and can hinder implementation [23, 24]. The current study aimed to reduce threats to staff acceptability by delivering a training programme to address various aspects of acceptability. For example, according to the technology acceptability model, there are several factors which influence technology acceptability in healthcare professionals including performance expectancy, effort expectancy, computer anxiety, computer self-efficacy and computer attitude [25]. For instance, according to Schaper and Pervan [25], performance and effort expectancy refer to the perceived ability of the technology to assist with an individual's ability to fulfil their duty and the ease at which it can be achieved. In preparation for training in the current study, therapists used various app features daily for 1 week and were asked to consider how certain features would complement their therapeutic style. Therapists also shared their ideas in group training to inform other therapists with similar therapeutic models. Regarding effort of use, therapists were required to review a client's app usage for a few minutes every session as a minimum but ultimately had the flexibility and responsibility to use the app as they deemed appropriate. Regarding computer anxiety and self-efficacy, in addition to the group training, therapists received ongoing one-to-one sessions with the primary researcher whom had a daily presence at the counselling service throughout the trial. Finally, regarding attitude and therapist engagement, the intervention therapists were selected based on (1) initial recommendations from the head of service and (2) expressed interest from therapists.

Therapist effects

There has been conflicting evidence exploring the impact of therapist effects on trial outcomes and there are various methods for estimating therapist effects [26]. Nonetheless, exploring therapist effects is important in implementation studies and for considering differences in treatment delivery across therapists. Due to the underpowered sample of the current feasibility trial, therapist effects for each of the quantitative outcomes will be estimated with intra-therapist correlations.

Counselling interventions

All participants will receive an active treatment in line with standard practice and will not be disadvantaged by participating in the trial. Participants will have access to the standard level of care at Sheffield UCS, which includes a wait period of typically 3–5 working days for the initial clinical assessment and 8–10 days between ongoing therapy sessions. This wait period varies throughout the year but the service agreement offers first contact within 10 days, and this is typically shorter than the NHS waiting times.

Counselling (TAU)

Up to 6 sessions of face-to-face counselling will be offered to participants in line with standard practice at Sheffield UCS. Sessions will be 50 min in length and the frequency of sessions will be determined through client-counsellor discussions. If participants require more than 6 sessions, treatment will continue outside of the trial and will be supported by the counselling centre. On such occasions, trial data will only be collected up to session 6.

Counselling supplemented with well-being app (enhanced intervention)

Up to 6 sessions of face-to-face counselling will be offered to participants in line with standard practice at the UCS. Sessions will be 50 min in length and the frequency of sessions will be determined through counsellor-client discussions. As well as the standard level of care, counselling sessions will be supplemented with discussion and guided use of a well-being app to promote engagement within and between face-to-face sessions. Clients and counsellors will have the opportunity to use the app on a computer tablet during counselling sessions to facilitate discussion and to aid the decision process for setting goals and reviewing client progress. Through these discussions, counsellors will review client app activity and guide them through various app features to decide which activities would be beneficial to use between face-to-face sessions. App features may include (1) daily behaviour tracking for mood, sleep, exercise, relationships, hygiene, water/caffeine/alcohol consumption, medication use and time spent outside; (2) reflective thinking through guided CBT, thought journaling, mindfulness and positive visualisation; (3) guided relaxation with breathing, meditation and body scan exercises; (4) peer-led support through anonymous online communities and private groups; and (5) setting/tracking short-term and long-term goals.

The app will provide daily prompts to encourage participants to log their mood/behaviour, but completion of various exercises relies on participants deciding when to use a feature, for example at the suggestion of their counsellor. Counsellors will also encourage participants to prepare for each face-to-face counselling session by reflecting on their diary entries and deciding on what they would like to address in the session. This reflective exercise may also occur at the start of each therapy session for participants who prefer to reflect on their activities with the support of their counsellor. During face-to-face sessions, counsellors will be encouraged to review app activity by asking participants to access their app account on the computer tablet, discuss participant's reflections and progressively adjust goals or exercises where appropriate.

Audio recording of sessions

Counselling sessions in the enhanced intervention will be audio-recorded, with participant consent, using the tablet in order to be more discrete than traditional recording equipment. Written consent for recording sessions will initially be sought during the research interview when participants join the trial. However, verbal consent will also be sought by counsellors at the start of each session to allow participants to opt-out of recording a particularly distressing counselling session. Sessions in the TAU condition will not be audio recorded to align with standard practice and because analysis is specific to discussing app activity, which is dependent on the enhanced intervention.

Primary feasibility measures

The yield of the feasibility trial is a series of specific primary and secondary outputs relating to a range of components that will inform the definitive trial. The primary outputs are recruitment, treatment preference, randomisation acceptability, treatment satisfaction and completion rate of follow-up measures. The secondary outputs are: app usage, intervention fidelity, client characteristics, therapeutic alliance and academic coping. Each of these primary and secondary outputs is described next.

Recruitment

The recruitment period for a definitive trial will be estimated from the current study by exploring the required time needed to reach 40 participants, whilst also considering the participant drop-out rate and counsellor

availability. Seasonal service demands will also be explored to distinguish peak service demand and to advise on the optimal time of year to implement a definitive trial. Service demand will be assessed by comparison of the annual reports provided from the service.

Treatment preference

During the research interview and prior to treatment allocation, participants will be informed about the two available treatment conditions and will be asked to indicate their preferred condition. Participants will also provide a primary reason for their decision before being informed of their treatment allocation. Participants who choose a condition incongruent with their allocation will be asked if the outcome affects their decision to join the trial. This information will be used to inform potential bias from participants being allocated to their preferred condition.

Randomisation acceptability

Once participants state their treatment preference and are informed of their actual treatment allocation, they will be asked whether being randomised to that condition increases the probability of them withdrawing from the study. This information, combined with the recruitment metrics, will be used to estimate the recruitment period and inform whether randomisation in a definitive trial would negatively impact on uptake.

Treatment satisfaction

Participant treatment satisfaction will be assessed with the 8-item Client Satisfaction Questionnaire (CSQ-8) [27], which will be emailed to participants the day after their last counselling session. CSQ-8 items refer to a client's overall service experience and are rated on a 4-point Likert scale (1 = "quite dissatisfied"; 5 = "very satisfied") whereby higher scores indicate greater satisfaction. Many counselling services report on client satisfaction to allow comparison to other services and to ensure that services respond to client feedback. Capturing client satisfaction will also allow comparisons between treatment conditions to explore whether the enhanced intervention had a positive or negative impact on a participant's service experience. A sub-sample of participants' service experiences will also be explored through telephone interviews after counselling completion. Finally, counsellor satisfaction in the delivery of the enhanced intervention will be assessed through a focus group once all participants have completed counselling.

Completion rate of follow-up measures

Completion rates will be assessed through the number of participants providing complete data for the 3-month follow-up measures (from consent date), 6-month follow-up measures and telephone interviews. The telephone interviews will also be used to ask participants how to optimise the follow-up response rate and maintain contact. Together, this information will be used to estimate the expected response rate and inform the design of a definitive RCT.

Secondary feasibility measures
App usage

App usage during counselling sessions will be assessed through audio recordings to determine how various features are discussed between participants and counsellors. The discussion of clients' app usage to monitor behaviours, thoughts, emotions and therapeutic exercises is an essential component of using feedback in therapy and in integrating the well-being app with counselling. Therefore, analysis of app discussion aims to identify dominant app features, inform potential moderators of therapeutic outcomes in the definitive trial and evaluate intervention fidelity (discussed below). Analysis of app discussion will also consider the added gain of using the purchased app version over the free version, by categorising discussion by features associated with either version of the app. A final exploration of app discussion will match app features with context-specific benefits, client characteristics and potential risk.

Participant app usage between counselling sessions will be addressed in follow-up telephone interviews to inform the acceptability of using a well-being app alongside counselling, and exploring the timeframe for how long the well-being app was useful for participants. Participant usage of the app overtime will also be explored through app data (e.g. log in times, duration of time spent using each feature), but this will be dependent on the availability of data and on participant consent to access app data.

Intervention fidelity

Intervention fidelity will be assessed through counselling audio recordings, a focus group with counsellors and telephone interviews with participants. Counselling recordings will be anonymised during transcription and assessed by two reviewers, the onsite researcher (unblinded) and an independent blinded researcher, to permit analysis of inter-rater reliability. A checklist will be provided to score the transcript content which will include the following themes, separately for counsellors and participants: (1) number of times app discussed; (2) duration of app discussion; (3) whether the tablet was used to view app activity; (4) whether there was reason to adjust app usage; (5) whether different app features were advised; and (6) whether there was a missed opportunity to discuss an app feature. Audio recordings will also be assessed against the BACP UCC competency

framework to determine clinical competency and to develop the framework for the definitive trial. Finally, intervention fidelity will be assessed in the counsellor focus group and participant interviews to explore challenges of integrating the app with counselling and to provide potential solutions.

Client characteristics

Client characteristics will be assessed collectively from (i) intake demographic data, (ii) counsellor notes from the initial clinical assessment, (iii) counsellor session notes and (iv) participant interviews. Combined, this information will be used to develop a client checklist and brief clinical guide to aid decision making on client appropriateness for using a well-being app. This guide is anticipated to inform the inclusion criteria for the definitive trial and will be shared with other UK UCSs interested in offering well-being apps to their students.

Therapeutic alliance

Therapeutic alliance will be assessed through the Working Alliance Inventory-Short Form [28] at the end of session 3 of counselling. WAI is a 12-item self-report measure completed separately by the counsellor and their client. Items refer to current views on the counsellor/client and are rated on a 5-point Likert scale (1 = "strongly disagree"; 5 = "strongly agree") whereby higher scores indicate stronger therapeutic alliance. Items also provide scores on three distinct components of therapeutic alliance including (1) agreement of therapy tasks, (2) agreement of therapeutic goals and (3) presence of an affective bond between clients and counsellors. These therapeutic factors will be compared across the enhanced intervention and TAU conditions to explore differences in therapeutic alliance and inform potential mediators of clinical outcomes to be tested in a definitive trial.

Academic coping

To complement the academic distress measure on the CCAPS [17], participants will be asked about their ability to cope academically during follow-up telephone interviews. During the interviews, participants will be asked whether their mental health has affected their studies (or vice versa) and whether they believe that counselling has contributed to their ability to cope academically. These findings will be used to explore the potential contribution UCSs have on academic coping, and will inform outcome assessment for a definitive trial.

Managing risk and adverse events

All stages of the feasibility trial will take place at the UCS and participants will have immediate access to professional mental health support. Counsellors involved in the trial will also have access to professional mental

health support through the duty counsellor in line with standard practice. Efforts have been made to reduce risk in the current study by ensuring that the design, training and delivery of interventions are informed by clinical judgement, and clinical competency is reinforced by the BACP competency framework and UCS clinical handbook. Furthermore, all decisions concerning participant allocation are informed by their assessing counsellor (see "Allocation" section). Counsellor training will also address participant withdrawal and how to report risk. In either event, every individual involved with the trial (e.g. admin, clinical and research) will be informed to report to the duty counsellor allocated at the start of each day. The reporting of adverse events will be recorded through (1) onsite researcher notes throughout trial, (2) therapist clinical notes from triage, (3) therapist notes from counselling and (4) duty therapist clinical notes. In line with the service clinical handbook, adverse events will be reported to the duty therapist and recorded electronically on the service's secure clinical scheduling system.

Data management

A primary researcher (author EB) will be selected to oversee all stages of the feasibility trial and will include the following responsibilities: (1) maintain primary contact with staff at the UCS; (2) deliver counsellor training; (3) deliver research interview with participants; (4) administer and score PHQ-9 and GAD-7 to determine participant eligibility; (5) offer ongoing support to counsellors by maintaining a physical presence at the UCS; (6) offer technical support of computer tablets; and (7) handle trial data from paper and electronic sources. As the primary researcher will oversee all stages of the feasibility trial and will handle all trial data, it was decided not to form a Data Monitoring and Ethics Committee; however, the primary researcher will regularly update with the head of service at the participating trial centre and authors AM and MB as research supervisors for the feasibility trial. Methods of planned data management have been approved by the trial sponsor REC, and have been implemented to be predominantly electronic to avoid human error and optimise data security.

Part of data management will require storing participant consent forms and documents from the research interview in a securely locked filing cabinet at the UCS. The filing cabinet will only be accessed by the primary researcher and the clinical team, if necessary. Therapy audio recordings from computer tablets will be immediately uploaded to an encrypted file (via UCS encrypted Wi-Fi) on the UCS computer system, and will not be stored on computer tablets. This process is automatic and will be triggered when the audio recording app is stopped. Only the primary researcher will have access to the encrypted folder and recordings will be anonymised

upon transcription. The remaining sources of clinical data (e.g. from questionnaires) will be administered online via unique survey links emailed to participants. Survey data will only be accessed through a secure account log-in which only the primary researcher will have access to. All data will be backed up on an encrypted external hard drive, accessed only by the primary researcher. Data will be stored in a Microsoft Access database on two encrypted USBs handled by the primary researcher.

Statistical analyses
Quantitative analysis
Analyses will be predominantly descriptive to characterise the study population and outline various feasibility metrics including recruitment rate, treatment preference, randomisation acceptability, treatment satisfaction and completion at follow-up. Whilst the sample size is not powered to detect significant differences between the TAU and enhanced intervention groups, data will be used to summarise outcomes from both groups to reveal preliminary trends and inform the design of the pilot trial from which estimates of effect and sample sizes will be calculated. Group comparisons will also be made between the demographic and baseline clinical measures to characterise the groups when they enter the trial. Determining potential baseline differences between the groups will inform whether the allocation procedure, which was dependent on clinical judgement, unintentionally created differences between the groups. Establishing these differences, or lack thereof, will further inform the potential group differences in clinical outcomes at the end of the feasibility trial. Outcome data will include the baseline prevalence and subsequent changes in depression (PHQ-9), anxiety (GAD-7), psychological functioning (CORE-10), student-specific mental health concerns (CCAPS) and emotional resilience (CD-RISC 10). Group summaries will also compare levels of therapeutic alliance (WAI) and treatment satisfaction (CSQ-8) in order to inform preliminary differences across treatments. No interim analysis will be performed; analysis will commence after completion of the 6-month follow-up. The distribution, variance and skewness of data will be initially explored to determine whether data should be described with parametric or non-parametric methods. Parametric descriptive statistics will include total score, mean, standard deviation, min, max and range. Non-parametric descriptive statistics will include total score, median, confidence intervals and inter-quartile ranges. Quantitative analyses will be performed with SPSS statistical software (version 22.0).

Approximately 40 h of therapy is anticipated to be recorded, transcribed and analysed. The conservative estimation for recordings considers several factors including

the following: (1) although participants will be offered ~6 counselling sessions, the services' median number of attended sessions is 2 and 4; (2) participants (and therapists) may decide not to record a session where the participant is particularly distressed; (3) trial budget available to fund transcription; and (4) feasibility trials are not required to be powered to detect significant effects but to provide sufficient preliminary indicators. Whilst data from the therapy recordings is qualitative in nature, they will be analysed with "quantitative" content analysis [29] whereby sessions will be scored to indicate intervention fidelity and implementation success. These scores will be achieved by using a checklist developed from the training materials to rate the extent to which therapists delivered the new intervention (see "Intervention fidelity" section). A random sample of 15 therapy hours will be assessed by an independent researcher, blind to the aims of the study, to permit analysis of inter-rater reliability.

Qualitative analysis
A number of feasibility factors will be explored qualitatively through counsellor clinical notes, a therapist focus group, and participant exit interviews; to explore the feasibility, acceptability and potential implications of supplementing counselling with a well-being app. The clinical notes will be extracted from the sessional notes taken as part of routine practice, except counsellors will additionally reflect on their experience of integrating the app and how the app fitted with their client/therapy style. These experiences will be explored in more detail at the end of the trial through a one-off therapist focus group. The participant exit interviews will take place once clients finish counselling and thus may occur throughout the trial depending on how early clients were recruited and how many counselling sessions they agreed to have with their therapist. The aims of the exit interviews are threefold: (1) to capture clients' experiences of the new intervention (and indirectly inform intervention fidelity); (2) to distinguish areas of improvement for research design; and (3) to identify whether counselling contributed to their ability to cope at university. Data from the client interviews, therapist focus group and clinical notes will be analysed flexibly and explorative with thematic analysis to allow themes to emerge from the data and to allow comparisons across different data sources [30]. By exploring themes across various data sources, the current study aimed to provide a rounded and comprehensive account for the following: (1) how well the app was integrated into counselling (according to clients, therapists and researchers) and (2) the potential risks/benefits of integrating an app with counselling, if implementation is successful. Qualitative data will be analysed with NVivo (version 11).

Discussion

Using a mixed-methods approach incorporating quantitative and qualitative data, this study will address a range of factors concerning the feasibility of supplementing counselling with guided use of a well-being app for university students experiencing anxiety or depression. Through this exploration, the primary feasibility outcome will determine whether it is possible to incorporate, review, and discuss participant app usage during face-to-face counselling sessions in a manner that is potentially beneficial to therapeutic outcomes. For this reason, the study design offers an active control to mimic standard practice and permit preliminary comparisons to be made with the enhanced intervention. By comparing the enhanced intervention with a condition mimicking standard treatment (TAU), this study will shed light on whether potential differences in group outcomes could be accountable by the addition of a well-being app alongside standard care. However, whilst this feasibility trial is not powered to detect significant differences between group outcomes, it will allow the identification of trends to inform the hypotheses for a definitive RCT. Furthermore, combined analysis on counselling recordings, interviews and a focus group on the enhance intervention will reveal possible treatment mechanisms which can then be assessed quantitatively in a fully powered trial.

A key goal of this feasibility trial is to explore the feasibility of the planned processes and document the issues that arise throughout the training, implementation, delivery and evaluation of research design and overall intervention. Therefore this study focuses on demonstrating the feasibility of offering a new treatment option to university students, and to review the potential implications for improving therapeutic outcomes. To address the first requirement, primary feasibility metrics will record: recruitment rate, treatment preference, randomisation acceptability, treatment satisfaction and completion of follow-up measures. However, if the new intervention is shown to be feasible, it is also important to understand the potential risks, implications and mechanisms to be explored in a definitive trial. Therefore, the secondary feasibility metrics will address app usage, intervention fidelity, therapeutic alliance and a range of clinical outcome measures monitoring mental health symptoms specific to university students. With anxiety and depression as the two most prevalent mental health concerns in students, participant eligibility will be determined through two clinical diagnostic tools, PHQ-9 and GAD-7, used widely in psychological services.

The planned enhanced intervention combines the benefits of face-to-face counselling with the flexibility of guided self-help, for university students experiencing anxiety and depression. By combining two treatment options which are typically offered separately, the current

study aims to address a number of challenges USCs experience. The most prominent challenges have been supporting a growing student population with short-term therapy that fits within the academic calendar. Through these challenges, UCSs have experienced increased waiting lists, higher rates of treatment drop-out and more demand for support during evenings, weekends and university holidays. Therefore, by combining face-to-face counselling with guided self-help support and behavioural tracking tools on a mobile app, the current study aims to demonstrate a preliminary impact on engagement, drop-out and therapeutic outcomes. Furthermore, by encouraging self-help tools between face-to-face sessions, the current study aims to offer ongoing support to students and optimise therapeutic time between clients and counsellors. If this new treatment option is shown to be feasible, the current study has potential to encourage flexible working styles and enhance existing face-to-face time without necessarily requiring more therapy sessions. These opportunities, amongst improving training, will be the primary aims of a definitive RCT following a pilot trial to be planned beyond the current feasibility study.

Endnotes

[1]The confirmation letter from REC has been submitted as Additional file 1.

[2]Based on referrals across 2011/12-2013/14 academic periods.

[3]Buddy App was availble during the original app search, but is no longer publically available.

Additional file

Additional file 1: Trial ethics approval letter. (PDF 29 kb)

Funding

Availability of data and materials

Data is not anticipated to be publically available. Study materials are available from authors on request.

Authors' contributions

EB, AM and MB designed the overall intervention study and drafted the manuscript. EB aided the group training and participated in the data collection. All authors made intellectual contributions to the work and approved the final manuscript.

Competing interests

The authors declare that they have no competing interests.

Consent for publication

It is not applicable; individual participant's data will not be included in any form.

Ethics approval and consent to participate

This study received ethical approval from the University of Sheffield, Department of Psychology, Research Ethics Committee (REC) on 05/01/2016 (ref: 006171). The preliminary evaluation study of the well-being app which informed manualised training for the feasibility trial also received ethical approval from the University of Sheffield, Department of Psychology, REC on 17/11/2015 (ref: 06727).

External scientific review

The protocol for the current feasibility trial has undergone independent scientific review by David Saxon (d.saxon@sheffield.ac.uk), Centre for Psychological Services Research, Mental Health Group, ScHARR, The University of Sheffield, Regent court, 30 Regent Street, Sheffield, S1 4DA.

Trial sponsor

University of Sheffield, Western Bank Sheffield, S10 2TN, United Kingdom (tel: +44 114 222 2000; email psychology@sheffield.ac.uk. Website: www.shef.ac.uk The trial sponsor research ethics committee ethically reviewed, and approved, the current feasibility trial including the study protocol and all associated study materials. The role of the trial sponsor extends beyond the current study, oversees all research activities related to the doctoral research programme undertaken by author EB, and is supervised by authors AM and MB.

Trial participating centre

University of Sheffield Student Counselling and Wellbeing Service, 36 Wilkinson Street Sheffield, S10 2GB, United Kingdom (tel: +44 114 222 9684; email ucs@sheffield.ac.uk). Website: www.shef.ac.uk/ssid/counselling. The interventions in the current study will be held at the trial participating centre and will be delivered by counsellors at the centre. Potential participants (help-seeking university students) who approach the trial participating centre will be recruited by counsellors from the centre. The head of service at the trial participating centre (Louise Knowles; see acknowledgements) will be involved, and will oversee, every stage of the feasibility trial.

Declarations

Author details

[1]Department of Psychology, University of Sheffield, Sheffield S10 2TN, UK. [2]Centre for Psychological Services Research, Department of Psychology, University of Sheffield, Sheffield S10 2TN, UK.

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Appendix A3

Published version of an article in T4i conference short article

Therapist experiences of supplementing counselling with guided use of a well-being mobile phone app

Speaker: Emma Broglia*   T4I communication type : Academic/Research
Other authors: Abigail Millings, Michael Barkham
Department of Psychology, University of Sheffield, UK

1. Overview
This article presents findings from a focus group exploring therapist's experiences of supplementing counselling with guided use of a well-being app in a student counselling setting. Preliminary findings address the implementation, acceptability, usage, and potential implications described during the therapist focus group.

2. Background
University counselling services (UCSs) face a unique challenge to offer short-term therapeutic support to students presenting with complex mental health needs, and in a setting which suits the academic timetable [1,4]. In addition, new government initiatives to widen university participation have increased demands for student services without the necessary funds to recruit additional therapeutic staff [2]. The recent availability of mobile phone applications (apps) provide an opportunity to supplement face-to-face therapy and have the potential to reach a wider audience, maintain engagement between therapy sessions, and enhance therapeutic outcomes. Therefore, the present study aimed to establish the feasibility of supplementing counselling with guided use of a well-being app. The reported focus group contributes to the ongoing feasibility trial comparing counselling alone, against counselling supplemented with guided use of a wellbeing mobile phone app in university students experiencing anxiety or depression.

3. Methods
The feasibility trial recruited 40 university students with moderate anxiety (score ≥ 10 on the Patient Health Questionnaire, PHQ-9 – [5] or depression (score ≥ 10 on the Generalised Anxiety Disorder Scale, GAD-7 – [6]. Students were allocated to one of two treatment conditions: 1) counselling alone (control); or 2) counselling supplemented with guided use of a well-being app ([3], intervention). Students in the control condition received ~6 counselling sessions within a 6-month period; in line with standard practice. In addition to the standard level of support, students in the intervention condition received therapist advice on using a well-being app to: 1) track moods and behaviours; 2) reflect on diary entries; 3) set goals; 4) complete exercises to relax and defuse negative emotions; or 5) interact with anonymous online communities. The usage, acceptability, feasibility, and potential implications of the intervention will be assessed through counselling session recordings, telephone interviews with students, and a focus group with therapists. Preliminary results from the therapist focus group will be discussed.

3.1 Ethical statement
Ethical approval was provided by the University of Sheffield Department of Psychology Research Ethics Committee (REC) before advertising for recruitment.

4. Results
Five therapists from the intervention condition took part in a focus group to discuss their experiences of supplementing counselling with a well-being app. Thematic analysis identified two prominent themes – feasibility and facilitation. The feasibility theme contained sub-themes which refer to the acceptability and implementation of the intervention including: 1) therapist commitment and engagement; 2) managing client expectations; and 3) fit with clients and therapy style. With successful implementation, therapists described using the app as a short-term practical solution to facilitate the therapeutic process. The feasibility theme also contained sub-themes that could interfere with the acceptance and implementation of the intervention, including: 1) therapist resistance to change and protection; 2) misperceptions of research; and 3) misunderstandings of intended use. The facilitation theme refers to the potential implications and mechanisms for facilitating the therapeutic process; whereby supplementing counselling with a well-being app showed potential to teach students about self-awareness of mental health and how to become their own therapist when they are ready to leave therapy.

5. Discussion
This feasibility trial aimed to identify the acceptability and potential implications of supplementing counselling with guided use of

a well-being app. In particular, by using an app alongside counselling to track moods/behaviours and complete wellness exercises, this study aimed to identify implementation strategies to support therapeutic engagement between counselling sessions and enhance outcomes. Analysis on a therapist focus group revealed that integrating the app with therapy relied on therapist commitment, client expectations, and fit with therapy style. Successful implementation showed potential to facilitate the therapeutic process, whereas implementation difficulties were at risk of misperceptions and resistance.

6. Conclusion

These results inform the training needs and knowledge base for university counselling services that are interested in being more research active, or are considering to offer well-being apps to students. Our findings highlight factors which interfere with the acceptance and implementation of a new intervention and give rise to potential misperceptions of research. Our findings also suggest that apps have the potential to promote student self-awareness and responsibility of mental health.

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Appendix A4

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Challenges to addressing student mental health in embedded counselling services: a survey of UK higher and further education institutions

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Challenges to addressing student mental health in embedded counselling services: a survey of UK higher and further education institutions

Emma Broglia [a], Abigail Millings [a] and Michael Barkham [a,b]

[a]Department of Psychology, University of Sheffield, Sheffield, UK; [b]Centre for Psychological Services Research, Department of Psychology, University of Sheffield, Sheffield, UK

ABSTRACT

Background: with reports continually demonstrating increased demand and severity of student mental health needs, it is important to gain a fuller understanding of the impact on embedded student counselling services. Aims: to identify (1) service similarities; (2) factors which impact on services; (3) characteristics of service users; and (4) identify the use of therapeutic technology (e.g. online self-help). Methods: an online survey was completed by 113 heads of UK student counselling services across Higher Education (HE), Further Education (FE), and Sixth Form Colleges (SFCs), to capture service data from the academic year 2013/14. Results: students predominantly received high-intensity support (e.g. Counselling) and referrals increased over 3-years. Conclusion: challenges to embedded counselling services and their implications for development are discussed.

Introduction

In the UK, student mental health within Higher Education Institutions (HEIs) has been at the forefront of the political agenda with recommendations from the Higher Education Policy Institute (HEPI) to collect institutional data on mental health services (see Brown, 2016). Many reports have highlighted the growth of the student population alongside increased demands for student counselling (e.g. Royal College of Psychiatrists Report, 2011; Storrie, Ahern, & Tuckett, 2010). A longitudinal study at one UK HEI found evidence that the psychological distress of students rose on entering university and did not return to pre-university registration levels for the duration of their course (Bewick, Koutsopoulou, Miles, Slaa, & Barkham, 2010). Similarly, a web-based survey across four UK HEIs found approximately one-third of students reported clinical levels of psychological distress (Bewick, Gill, Mulhern, Barkham, & Hill, 2008). However, this concern has also extended to Further Education Institutions and Sixth Form Colleges (Warwick, Maxwell, Statham, Aggleton, & Simon, 2008). In addition, the concern about student mental health has been made at a global level (Rückert, 2015).

In response to this increasing need, counselling services in the UK have been challenged to respond to and demonstrate the effectiveness of the therapeutic support offered (e.g. Randall & Bewick, 2016). Uniquely, support services within such establishments are required to work within a cycle of semesters and vacations that do not apply to the general population, however the latest

HEPI report recommends that students have access to these services even when away from campus (Brown, 2016). Related, and contributing to this challenge, is the fact that there is a great deal of variation in the information collected across services, which hampers benchmarking and the identification of areas of development across different sectors.

In terms of services offered, in FE and SFCs the types of support may include individual or group counselling and may extend to classroom interventions involving teachers or parents. In HE services, in addition to one-to-one support, students may also be encouraged to use guided self-help, peer-to-peer support, or online help (Mair, 2016). Moreover, the use of eTherapies (i.e. therapeutic advice provided via the internet or telephone) have become popular in recent years, but it is unclear which types of eTherapy have been adopted by services nor is it clear which types of eTherapy students may benefit from (Sucala et al., 2012). Offering different modes of support is necessary to suit the diverse needs of students. However, it also creates difficulties for comparing outcomes in different service sizes and educational settings. Making comparisons across services is advantageous because it can inform service development, demonstrate effectiveness, and build evidence to support bids for institutional funding (Murray, McKenzie, Murray, & Richelieu, 2015). The latter is particularly important in the current economic climate since the reduction of government funding has led to closures of student counselling services in FE (Caleb, 2014). In HE, new policies to widen participation and raise tuition fees have created new challenges for students and counselling services. For example, student debt has been linked to poorer psychological functioning as well as considerations for dropping out of education (Cooke, Barkham, Audin, Bradley, & Davy, 2004; Walsemann, Gee, & Gentile, 2015). Furthermore, early reports from the widening participation scheme anticipated increased reports of student mental ill-health in response to more students from disadvantaged backgrounds entering HE (See Department for Business Innovation & Skills report, 2013).

The challenges of student counselling services have been documented widely and continue to be a concern (Kreß, Sperth, Hofmann, & Holm-Hadulla, 2015; Prince, 2015). In fact concerns for meeting higher demands in student counselling services were reported as early as 1969 and yet demand continues to be a prominent issue (Goldberg, 1980; Holm-Hadulla & Koutsoukou-Argyraki, 2015). This ongoing growth of students entering FE and HE has shaped embedded counselling services to offer new ways of providing support. One response to managing demand has been limiting counselling to 6 sessions. However, the introduction of very short-term support has raised concerns as to whether effective support can be delivered within these time restraints (Mair, 2016). Despite these concerns, client feedback suggests that counselling services contribute to students' ability to cope academically (McKenzie, Murray, Murray, & Richelieu, 2015). However, as the severity and complexity of student mental health increase, there are growing numbers of students approaching embedded counselling services that would otherwise seek help from the National Health Service (NHS; Stallman, 2010). Furthermore despite limiting the number of counselling sessions, the growth of student referrals has lengthened waiting times (Mowbray et al., 2006). In the student counselling context, the length of the waiting list is further challenged by students having limited access to support outside of academic term times or during course placements.

In response to the unique challenges of FE and HE, student counselling services have introduced alternative support in addition to traditional face-to-face counselling and the HEPI further recommends that services sign-post alternative support resources; including self-help and mobile apps such as the Expert Self-Care Student mobile app (Brown, 2016). The use of alternative support has coincided with the availability of therapeutic technology that has the potential to reach more individuals in a shorter period of time and without the need to regularly attend the counselling service. These attributes are particularly relevant in FE and HE as students have been known to seek help outside of traditional office hours, particularly during evenings, nights and weekends (Gatti, Brivio, & Calciano, 2016). Offering alternative support that can be maintained at a distance also shows potential to support students on course placements who would otherwise not have access. One of the most recent advancements has been from mobile phone apps supporting mental well-being. However there are concerns about quality and risk assessment (Grundy, Wang, & Bero, 2016).

In light of the increasing pressure on embedded counselling services, the current study aimed to compare service data across service size (e.g. small, medium, and large) and sector (i.e. Further Education, Sixth Form Colleges, and Higher Education) to establish the following: (1) service similarities (e.g. use of staff); (2) factors which impact on counselling services (e.g. attended counselling sessions); (3) factors which characterise students/service users (e.g. uptake of different types of support); and (4) identify the use and interest in offering therapeutic technology as a means to address service and client factors (e.g. online self-help).

Method

Design

An online survey was devised based on questions reported in annual service reports made publicly available by university and college counselling services[1]. The survey was also informed by an executive committee representing Heads of University and College Counselling Services (HUCS) from FE and HE. The final scope of questions covered the following areas: (1) service characteristics (e.g. size of client pool, years of service, Full Time Equivalent of paid and volunteer therapeutic staff); (2) factors affecting services (e.g. attended counselling sessions, waiting times, and use of clinical outcome measures and associated problems); (3) characterising service users (e.g. referrals for different types of support, and 3-year demand); and (4) types of alternative support available through the service and the head of services' interest in offering therapeutic technology (e.g. self-help, peer-to-peer, online communities, and mobile phone apps). To ensure clarity and consistency across survey answers, definitions were provided within the survey (see Appendix 1). Unless stated otherwise, questions referred to the previous academic year (2013/14) and reminders of this time frame were stated within each question.

Survey functionality and distribution

The survey questions were displayed electronically on a powerful online platform (https://qualtrics.com/) that enabled participants to complete the survey across multiple sittings. This functionality required participants' email addresses and, although answers were confidential, they were not therefore anonymous. To allow services to contribute anonymously, a second web link to the survey was created, but this version could only be completed in one sitting. Heads of student counselling services were contacted through a professional mailing list by the chair of the HE counselling sector on behalf of the researchers. The aim of the initial contact was to collect online consent to be contacted by researchers with a unique link to the survey, and to provide the link to the anonymous survey for services willing to complete the survey in one sitting. During the initial contact, the following information was provided: (1) electronic copies of survey questions; (2) a web link to an online consent form to receive a unique web link; and (3) a web link to the anonymous survey version. To promote data integrity and to enable clearer comparisons of service data, question responses were multiple choice with options to provide additional comments on each page. An exception was one question capturing therapists' difficulties when using clinical outcome measures, which was an open comment box with unlimited entry.

Participants

A total of 113 heads of service completed the survey comprising 72 who provided emails through the online consent form shared on a professional mailing list (see above) and a further 41 who completed the survey anonymously. Whilst the total number of heads of services whom accessed the professional mailing list is unknown, there are approximately 160 student counselling services in the UK. Moreover, a previous annual survey distributed through the same professional mailing list

captured data from 63 services in 2011/12 (see Dailey & Abbott, 2013), highlighting a stronger response rate for the current study.

The 113 counselling services were drawn from the following sectors: SFCs ($n = 11$, 9.7%), FE ($n = 37$, 32.7%), and HE ($n = 65$, 55.6%). The study received ethical approval from the University of Sheffield Research Ethics Committee before expressions of interest were sought from heads of service (Ref:1078).

Analytic overview

As service facilities are determined by the level of support they have, both financially and in terms of staffing, service characteristics are anticipated to vary according to service size. Therefore, survey data has been grouped into small, medium, and large based on tercile cut-points, within each sector, from the total number of students registered at each institution.[2] Moreover, grouping services according to the number of student registrations is hoped to be informative by enabling heads of service to make comparisons and reflect on their own service. The sizes of the groups were operationalised as follows: (1) small (~12,000 students; $n = 22$, 33.8%); (2) medium (12,001–18,673 students; $n = 22$, 33.8%); and (3) large (18,674 + students; $n = 21$, 32.4%). FE institutions were grouped into: (1) small (~8,000 students; $n = 14$, 37.8%); (2) medium (8,001–15,000 students; $n = 13$, 35.1%); and (3) large (15,001 + students; $n = 10$, 27%). SFCs were grouped into: (1) small (~1,927 students; $n = 4$, 36.4%); (2) medium (1,928–2,400 students; $n = 4$, 36.4%); and (3) large (2,401 + students; $n = 3$, 27.3%).

Analysis of survey data is predominantly descriptive with the goal of providing an initial descriptive account of UK student counselling services, given the limited research on UK services. As data were normally distributed, the mean, standard deviation and range have been provided to characterise services. Service structure was characterised as the number of years the service had been available and the full-time equivalent (FTE) of paid/volunteer therapeutic staff across low and high-intensity support (e.g. Counselling, Cognitive Behaviour Therapy (CBT), psychotherapy). Factors affecting services were identified by the typical and maximum number of attended and unattended counselling sessions; average, minimum and maximum waiting period for initial and ongoing counselling sessions; the administration of routine outcome measures (ROMs); and difficulties experienced while using ROMs and other assessments. Given the qualitative nature of data capturing difficulties experienced using ROMs, thematic analysis (see Braun and Clarke, 2006) was performed by author EB to provide prominent themes across all services. Themes were determined by grouping comments which were similar in nature (e.g. describing inconsistent use of ROM's across staff). Themes were corroborated by author MB, before weighted percentages were calculated to establish overlapping experiences across heads of service.

Pearson correlations were calculated to establish the relationships between the waiting periods and the number of attended and unattended counselling sessions (defined as: 'sessions in which the student did not attend or cancelled after referral'). Service users were characterised by the percentage of student referrals out of the total number of students registered at the institution that year; the percentage of referrals for low and high-intensity support; and overall referrals over a 3-year period to identify changes in demand. The final analysis presents the percentage of services that previously, currently, or would like to use a range of alternative support resources including a range of therapeutic technologies.

Results

Service years

Table 1 presents the number of years counselling services had been available across size and sector. Large HE counselling services had been available the longest, followed by medium services, and small services. This pattern is reflected in FE whereas in SFC, large services had been available the longest followed by small and medium services.

Table 1. Duration of existence of embedded counselling service (in years).

Sector & size	N	Mean	SD	Min-Max
HE	65			
Small	22	20.23	11.25	2–50
Medium	22	27.29	9.42	14–48
Large	21	28.43	9.23	8–46
FE	37			
Small	14	14.32	6.90	2–25
Medium	13	16.20	3.99	9–23
Large	10	17.44	5.15	12–26
SFC	11			
Small	4	13.50	6.02	7–20
Medium	4	11.50	6.58	3–18
Large	3	18.67	7.09	11–25

FTE of therapeutic staff

Irrespective of sector or size, all counselling services had more high-intensity therapeutic staff than any other available role (see Table 2). This difference was less pronounced in the FE sector, while in SFC the only role other than high-intensity was unpaid. Across service size, large services had the most high-intensity counsellors, whereas medium services had the most Mental Health Advisors (MHAs; defined as 'someone whose specific role is to assess the impact of mental health needs on academic ability and provide information about mental health issues and the services/support available') and small services had the most unpaid/trainee counsellors.

Referrals

In HE the majority of students were referred to high-intensity support and this was consistent across service size (see Table 3). A small percentage of students attended for only the first appointment (and did not go on to receive counselling)[3], and this was highest in medium services which was more than twice as many than small HE services. Medium HE services also reported the most students being referred for low-intensity support (e.g. one-off workshops, short groupwork, or psychoeducation). This pattern of referrals matched FE and SFC, and overall SFC reported the highest percentage of referrals for high-intensity support, but this was also the only form of support reported. Irrespective of the intensity of support, both FE and HE services experienced increased demand across the 3-years

Table 2. FTE of therapeutic staff across HE, FE and SFC counselling services.

Service size	N	High-intensity	Low-intensity	Groupwork	MHA	Unpaid	Total
HE							
Small	18	1.86	0.09	0.08	0.95	1.37	4.35
Medium	19	3.71	0.43	0.01	1.92	0.62	6.69
Large	18	4.38	0.32	0.00	1.86	1.35	7.91
Total	*55*	*9.95*	*0.84*	*0.09*	*4.73*	*3.34*	*18.95*
FE							
Small	11	1.11	0.09	0.12	1.00	0.13	2.45
Medium	10	0.93	0.44	1.11	0.76	0.63	3.87
Large	9	1.08	0.00	0.00	–	0.37	1.45
Total	*30*	*3.12*	*0.53*	*1.23*	*1.76*	*1.13*	*7.77*
SFC							
Small	3	0.75	0.00	0.00	–	0.20	0.95
Medium	4	0.37	0.00	0.00	–	0.69	1.06
Large	3	1.00	0.00	0.00	–	0.22	1.22
Total	*10*	*2.12*	*0.00*	*0.00*	*–*	*1.09*	*3.23*

MHA = Mental Health Advisor defined as 'someone whose specific role is to assess the impact of mental health needs on academic ability and provide information about mental health issues and the services/support available'. Missing data (HE: small = 4; medium = 3; large = 3; FE: small = 3; medium = 3; large = 1; SFC: small = 1; medium = 0; large = 0).

Table 4. The typical and maximum number of attended counselling sessions recorded in 2013/14.

Service	N	Typical attended sessions (n)			Maximum attended sessions (n)		
		Mean	SD	Min-Max	Mean	SD	Min-Max
HE	60						
Small	20	4.40	3.17	1–12	24.50	7.50	12–34
Medium	19	3.15	1.64	1–6	22.92	10.76	6–46
Large	21	3.29	1.64	1–6	23.20	6.74	11–36
FE	31						
Small	12	3.62	2.04	1–7	20.29	5.90	16–32
Medium	10	3.40	2.30	1–6	17.21	9.33	8–32
Large	9	4.20	2.17	1–6	28.25	11.50	14–39
SFC	6						
Small	3	5.50	6.36	1–12	25.50	7.78	20–31
Medium	2	4.75	2.36	1–7	25.00	10.23	10–32
Large	1	3.00	na	1–6	na	na	na

Missing data (HE: small = 2; medium = 3; large = 0; FE: small = 2; medium = 3; large = 1; SFC: small = 1; medium = 2; large = 2).

Unattended counselling sessions

In HE, the annual number of unattended counselling sessions increased with service size (small: mean = 275.14, SD = 209.71, min = 23, max = 857; medium: mean = 487.01, SD = 239.39, min = 191, max = 868; and large: mean = 682.88, SD = 437.57, min = 151, max = 1368). In FE, medium counselling services reported the highest number of unattended counselling sessions (mean = 265.25, SD = 241.22, min = 108, max = 622), followed by large (mean = 194.67, SD = 61.28, min = 124, max = 233) and small with the fewest (mean = 154.40, SD = 65.01, min = 74, max = 213). In SFC, small services reported the fewest unattended counselling sessions compared to FE and HE (mean = 115.09, SD = 106.13, min = 9, max = 362.14), however, medium and large services did not report on unattended sessions.

Average waiting periods

Inspection of Table 5 demonstrates that the average waiting period for the initial face-to-face appointment was 6 working days in large HE services and 7 working days for small and medium services. After this, students waited approximately 17–18 working days between ongoing counselling sessions across service size and sector. There was a large variation in the potential waiting period across service sizes, which was the longest in small services for the initial appointment and in large services for ongoing sessions.

Table 5. Wait period (in working days) for the initial assessment and between ongoing counselling sessions in higher education, further education, and sixth form colleges.

Service Size	N	Initial waiting period				Ongoing waiting period			
		Mean	SD	Min	Max	Mean	SD	Min	Max
HE	57								
Small	19	6.83	4.56	2.00	18.00	17.64	10.48	18.00	33.00
Medium	18	6.74	2.78	3.00	12.40	16.57	8.51	12.40	34.00
Large	20	6.14	3.59	0.00	12.50	16.97	13.90	12.50	43.59
FE	29								
Small	13	8.05	3.83	4.00	13.20	8.58	3.53	13.20	15.00
Medium	9	9.12	4.80	4.00	13.50	17.50	6.61	13.50	25.00
Large	7	6.36	1.67	4.80	8.00	10.98	9.46	8.00	27.50
SFC	5								
Small	3	7.50	3.54	5.00	10.00	20.00	14.14	10.00	30.00
Medium	2	7.63	4.39	3.00	12.50	8.00	2.65	12.50	10.00
Large	0	–	–	–	–	–	–	–	–

Missing data (HE: small = 3; medium = 4; large = 1; FE: small = 1; medium = 4; large = 3; SFC: small = 1; medium = 2; large = 3).

There were no significant associations between the waiting periods and the number of unattended sessions (Initial: $r = .28$, $p = .16$; ongoing: $r = .28$, $p = .20$), suggesting that factors aside from the waiting list affect students' ability to attend counselling sessions. There were also no significant associations between the waiting periods and the number of counselling sessions students attended (Initial: $r = .06$, $p = .74$; ongoing $r = .03$, $p = .88$). This was also true for the maximum waiting periods and the number of counselling sessions attended (Initial: $r = .06$, $p = .74$; ongoing: $r = .09$, $p = .88$). However, there was a significant negative association between the number of counselling sessions attended and the number of unattended sessions ($r = .48$, $p = .01$), suggesting that students were less likely to cancel sessions the further into counselling they were.

Compared to HE, FE services reported longer waiting periods for both the initial appointment and ongoing counselling sessions, with the longest initial wait found in medium sized services (Table 5). For ongoing counselling sessions, students waited the least in small services, which was also less than the waiting period for ongoing sessions in all HE services. This was also true for the maximum waiting period for ongoing sessions in FE which was typically 10 days fewer than HE. However, few FE services provided data on the waiting period as follows: 4 small services (40%), 3 medium services (30%), and 4 large services (40%). SFCs also had missing data, with only 5 services (36%) contributing data on the waiting periods. Of the data provided, SFCs showed a similar waiting period to FE services for the initial assessment with students waiting approximately 8 working days to be seen. The longest waiting period in SFCs, for both the initial and ongoing counselling sessions, was found in small services, whereas medium services reported the shortest waiting period overall.

Measuring outcomes

Of the various outcome measures available, 39% (total $n = 61$) of HE services used the Clinical Outcomes in Routine Evaluation-Outcome Measure (CORE-OM; see Barkham et al., 2010), 5% used the Patient Health Questionnaire (PHQ-9; Spitzer, Kroenke, & Williams, 1999), and 3% used the Counseling Center Assessment of Psychological Symptoms (CCAPS; Locke et al., 2011). A further 47% did not use a validated clinical measure although 15% used their own assessment or feedback form. The final 6% did not report on their use of clinical outcome measures. A total of 20% of services used more than one clinical measure. In FE services, only 6 services (42%) used a validated clinical measure, which was predominantly the CORE-OM, and the remaining 48% used their own service evaluation form or questions concerning the impact of counselling services on students' ability to cope academically. In SFCs, only one service (9%) used a validated clinical measure (PHQ-9) but also reported that 2013/14 was the first year of administration.

In HE, 92% of medium and large services and 79% of small services administered measures at initial screening (i.e. pre-treatment). Only 25% of medium and 62% of large services administered measures at the end of therapy (post-treatment). However, 82% of small services collected post-data. Few HE services administered measures every session representing only 8% of small, 23% of medium and 11% of large HE services. Services in FE and SFCs were less likely to use clinical outcome measures compared to HE with only 36–50% collecting pre-data and 43–50% collecting post-data. However, SFCs were most likely to collect data at every counselling sessions compared to FE and HE (75–100%).

Problems experienced with clinical outcome measures

Of the 65 HE institutions, 37 (57%) reported problems experienced when using (or deciding not to use) a ROM. Ten key issues were raised: (1) low return rate for follow-up data ($n = 30$, 81%); (2) missing data from students with unplanned endings ($n = 28$, 76%); (3) inconsistency across staff using/not using measures ($n = 25$, 68%); (4) time consuming to use measures or to interpret/discuss/input/analyse results ($n = 24$, 65%); (5) difficulties analysing or reporting data/not having a dedicated member of staff ($n = 23$, 62%); (6) inconsistency in data across services and unable to

benchmark ($n = 15$, 41%); (7) concerns over differences between different clinical measures ($n = 13$, 35%); 8) concerns over students not wanting to complete forms ($n = 4$, 11%); (9) no UK normative sample for students ($n = 2$, 5%); and (10) concerns over students exaggerating distress to be seen quicker ($n = 1$, 3%).

Offering alternative support

To explore the types of alternative support available from student counselling services and how the types of support vary according to time and interest, services were asked to report on whether they offered a range of alternative support options in 2013, 2014, and whether they would like to offer any of the types of support listed including: email counselling, phone counselling, self-help books, online self-help, peer-to-peer, groupwork, eTherapy, online communities, and mobile phone apps. Responses were provided by HE services only, and of the 65 HE services in the survey, 46 services (71%) reported on the use and interest in offering alternative support. Percentages were calculated for the number of HE services which have used or would like to use each type of alternative support, with the most prominent including: email counselling, eTherapy, online communities, and mobile phone apps (see Figure 2). HE services differed greatly according the types of alternative support they offered and the types of alternative support they would like to offer. In small services, the use of email counselling, online communities and eTherapy reduced over time with little interest in keeping these services. By contrast, medium services showed increased popularity for email counselling and eTherapy, with declining interest in online communities. Large services also showed reduced interest in eTherapy, email counselling, but unlike small and medium services, large services showed slightly more interest in offering online communities in the future. The only form of alternative support that increased in popularity across all services was mobile phone apps to support mental health and well-being. FE and SFCs did not report on their use or interest in alternative therapeutic support.

Discussion

The aim of this study was to characterise UK embedded counselling services in HE, FE, and SFCs to determine their capacity to address the increasing number and severity of student referrals. As expected, the overall level of demand on services increased over a 3-year period and this trend was reflected in referrals, predominantly for high-intensity support. However, this only applied to HE and FE sectors and was particularly acute for HE in 2013. This is noteworthy because it coincides with the first student cohort affected by the rise in tuition fees, introduced in September 2012 (Bolton, 2014). Research has linked student debt with poorer psychological functioning and this relationship has been corroborated by literature even before the fee rise (Cooke et al., 2004). The increased demands for student counselling services may also be attributed to widening participation schemes as more students from more disadvantaged backgrounds are able to access HE and early reports anticipated an increase in the reporting of student mental ill-health (Kemp, 2002).

Despite subtle differences across the sectors, there was an overwhelming trend to utilise high-intensity therapeutic staff. The finding that services predominantly refer for high-intensity support suggests that students approach services when their mental well-being is already affecting their ability to cope. This severity also indicates that students are no longer a privileged group in society and demonstrate a higher prevalence of mental ill-health compared to the general population (Stallman, 2010). Together, these findings substantiate the need for preventative programmes across educational institutions to equip students with the skills (e.g. emotional resilience; see Brown, 2016) to manage their mental health. Such programmes would benefit from promoting help-seeking behaviour to encourage students to seek help before their mental needs are severe.

While not surprising that that the largest therapeutic role was for high-intensity support, the finding that a second prominent role was for MHAs may not have been foreseen. The growth of MHAs in student counselling services has been reported in previous literature and demonstrates a
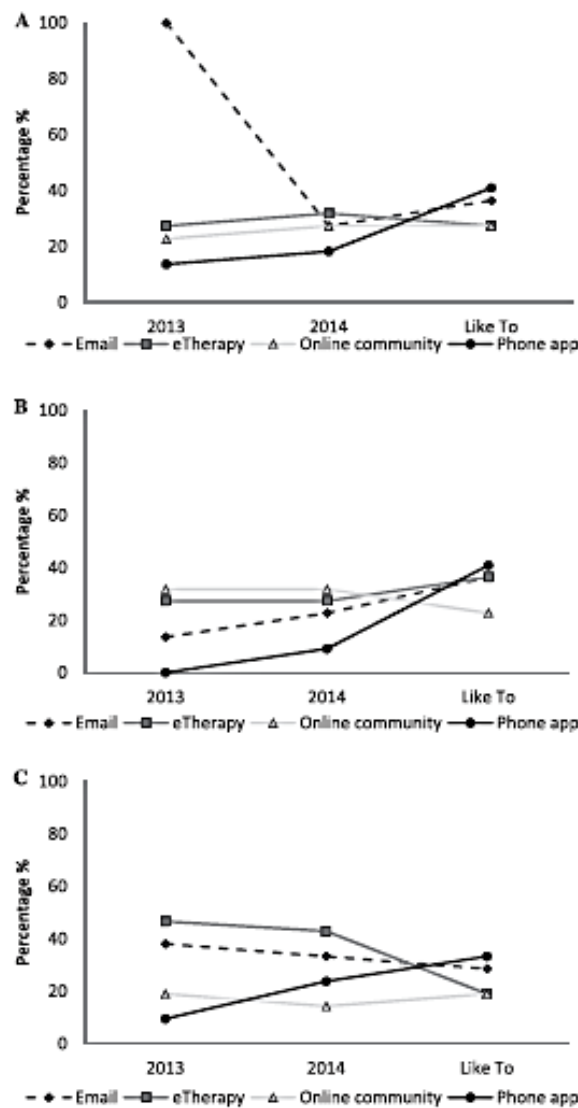
Figure 2. Use of alternative support in higher education counselling services. A = Small services (n = 18); B = Medium services (n = 20); C = Large services (n = 20).

promising response to recommendations from the Royal College of Psychiatrists report (2011). The recent availability of MHAs also reflects changes in service structure as educational institutions introduce dedicated roles to assess the impact of mental health needs on academic ability (see Blakely & Bragg, 2010). By offering specific types of support via such roles, student counselling services highlight the importance of supplying a therapeutic team that is trained and experienced in the student context.

Whilst student counselling services have traditionally offered short-term support, the number of counselling sessions offered has typically varied. This variation has also often changed in response

to increasing demands by means of managing longer waiting lists (Mair, 2016). Our findings suggest that two groups of students are likely approaching services: those who are adjusting to a new experience or task, and those in need of on-going therapy. Although the majority of students received short-term support, there have been concerns over the length of time students wait to be seen, particularly as higher demands have led to longer waiting lists (Mowbray et al., 2006). The waiting period has been a particular concern because there is mixed evidence to suggest that the mental health needs of individuals may worsen whilst waiting to be seen. However, they may also improve or show no change (Posternak & Miller, 2001). Despite prior concerns, our findings suggest that being on a waiting list does not lead to students needing more counselling sessions and they are not necessarily at risk of disengaging from therapy. This finding is likely due to the reasonable length of the waiting lists in FE/HE compared to the lengthy waiting lists reported in external counselling services (Dendridge, 2015).

In line with previous literature, the current study found that the CORE-OM was the most commonly used instrument in HE and FE sectors. However, almost half of services did not use a validated clinical measure and 15 per cent used their own feedback measures. It is difficult to see how some services will be able to survive in the absence of evidenced-based outcomes that can be benchmarked against relevant population norms. Collecting client feedback is advantageous as it contributes to the service evidence reported to governing bodies and is recommended to ensure that services are responsive to students' needs (Mental Wellbeing in Higher Education Working Group, 2015).

The current study aimed to distinguish problems experienced when using validated clinical measures to inform service development. Our findings identified several issues that concerned either students' use of clinical forms or their use across different therapists and services. The overarching themes centred on an absence of a culture of evaluation and a lack of strategic implementation that would enable collected data to be best used. The constant message of needing additional support in order to implement measures was evident. However, there are now brief measures that are under Creative Commons License and can be mounted free into electronic management systems: for example, CORE-10 and GP-CORE (Barkham et al., 2010). It is to be hoped that services not using a bona fide outcome measure change their practice as soon as possible. There were also concerns about using clinical assessments that do not capture student distress (e.g. academic, family, social anxiety, or substance misuse) or the absence of UK norms for student counselling. Interestingly a small percentage of services used CCAPS (Locke et al., 2011), which is a student specific clinical tool used widely in America and has been validated recently for use in the UK (Broglia, Millings, & Barkham, 2017).

In terms of offering alternative support, this appears particularly important in student counselling services because students often seek help during evenings and at weekends or in more accessible formats such as online or self-help support (Mair, 2016). The current study found particular interest in email counselling, eTherapy, online communities, and mobile phone apps. The finding that small and large services have reduced interest in email counselling and eTherapy, having used them previously, reflects a shift in interest as newer forms of therapeutic technology become available. The cost of new therapeutic technologies and devices are also important considerations for offering alternative support. For instance, it is not surprising that email counselling and video conferencing were used heavily in 2012/13 as they create little expense on a service budget that is already stretched. In similar light, the introduction of well-being apps offers alternative support which is substantially cheaper than the online self-help platforms currently available.

The recent surge of apps for mental well-being has sparked new research exploring the efficacy, effectiveness, and potential implications of using apps to support mental health (Powell, Chen, & Thammachart, 2017). One growing concern is the abundance of apps that are readily accessible by the public without the means to quality assess or determine the appropriateness for individuals to use apps. For example, a recent review of mental and physical health apps found that only 14 per cent had been designed with input from a healthcare professional (Sedrati, Nejjari, Chaqsare, & Ghazal, 2016). Interestingly, the review also found that although the majority of apps for physical health had been designed for medical professionals rather than patients, the majority of apps for

mental health had been designed for patients. Together these results highlight that mental health apps should be used with caution and that users could benefit from having professional guidance on the appropriate use of apps.

Cautions and future considerations

Caution should be taken when interpreting results and when drawing conclusions in comparison to individual service data. As there was limited information on embedded counselling services in HE, FE and SFCs, the basic task of the survey was to collect comparative service data that would profile services in order to provide a platform for future research. Moreover, whilst data have been collected on a large number of counselling services across the educational sectors, there was inevitably missing data; most noticeable in FE and SFC. This missing data raises awareness of the types of data currently being collected by embedded counselling services. This finding also highlights the need for guidelines (and encouragement) for collecting data which is informative for future service development.

Conclusion

In conclusion, the current study highlighted the marked severity of student mental health needs and the growing demand that is accelerating in the HE sector, with raised tuition fees and widening participation schemes a likely contributing factor. We found evidence of progress made with new roles (i.e. MHAs) but still a shortfall in the collection of routine outcome data. Finally, our findings demonstrate an overlapping interest in offering mobile apps to support student mental health, which show potential to address the challenges outlined in the current study.

Notes

1. See http://www.counselling.cam.ac.uk/general/reports for example reports.
2. The decision to split services for analysis was supported by the HUCS professional group as it was considered more informative than analysing the sample as a whole, as presented in a previous report (see Dailey & Abbott, 2013).
3. The reasons are unknown as to why this sub-group of students only attended the first assessment (i.e. whether they decided not to receive support), however it is unlikely due to students not meeting the criteria to receive counselling as such students would have been recorded in the low-intensity group.

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Notes on contributors

Emma Broglia is currently a post-doctoral researcher in the University Secretary's Office at the University of Sheffield. Her research interests include student mental health, embedded counselling services, help-seeking behaviour, and attainment in higher education.

Abigail Millings is a lecturer in Psychology at the University of Sheffield. Her research interests include attachment styles and the implementation of assistive technologies.

Michael Barkham is a Professor of Clinical Psychology and Director of the Centre for Psychological Services Research at the University of Sheffield. He has a long-term research interest in outcome measurement and the provision of psychological services and support to students.

ORCID

Emma Broglia   http://orcid.org/0000-0003-2137-8187
Abigail Millings   http://orcid.org/0000-0002-7849-6048
Michael Barkham   http://orcid.org/0000-0003-1687-6376

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Appendix B1

MeSH terms used in literature search engine for a systematic review on embedded student counselling between 2005-2015

(College[All Fields] AND ("students"[MeSH Terms] OR "students"[All Fields])) AND

Title/Abstract[All Fields] OR (("universities"[MeSH Terms] OR "universities"[All Fields] OR

"university"[All Fields]) AND ("students"[MeSH Terms] OR "students"[All Fields]))) AND

Title/Abstract[All Fields] AND ("counselling"[All Fields] OR "counseling"[MeSH Terms] OR

"counseling"[All Fields])) AND Title/Abstract[All Fields] OR ("psychotherapy"[MeSH

Terms] OR "psychotherapy"[All Fields])) AND Title/Abstract[All Fields] OR e-therapy[All

Fields]) AND Title/Abstract[All Fields] AND (Psychological[All Fields] AND

("diagnosis"[Subheading] OR "diagnosis"[All Fields] OR "symptoms"[All Fields] OR

"diagnosis"[MeSH Terms] OR "symptoms"[All Fields]))) AND Title/Abstract[All Fields] OR

Wellbeing[All Fields]) AND Title/Abstract[All Fields] OR ("anxiety"[MeSH Terms] OR

"anxiety"[All Fields])) AND Title/Abstract[All Fields] OR ("depressive disorder"[MeSH

Terms] OR ("depressive"[All Fields] AND "disorder"[All Fields]) OR "depressive

disorder"[All Fields] OR "depression"[All Fields] OR "depression"[MeSH Terms])) AND

Title/Abstract[All Fields] OR ("health"[MeSH Terms] OR "health"[All Fields])) AND

Title/Abstract[All Fields] OR ("Stress"[Journal] OR "stress"[All Fields])) AND

Title/Abstract[All Fields] OR (Academic[All Fields] AND performance[All Fields])) AND

Title/Abstract[All Fields] OR (Academic[All Fields] AND attainment[All Fields])) AND

Title/Abstract[All Fields] OR ("eating disorders"[MeSH Terms] OR ("eating"[All Fields]

AND "disorders"[All Fields]) OR "eating disorders"[All Fields])) AND Title/Abstract[All

Fields] OR (("eating"[MeSH Terms] OR "eating"[All Fields]) AND concerns[All Fields]))

AND Title/Abstract[All Fields] OR ("body image"[MeSH Terms] OR ("body"[All Fields]

AND "image"[All Fields]) OR "body image"[All Fields])) AND Title/Abstract[All Fields] OR

("sleep"[MeSH Terms] OR "sleep"[All Fields])) AND Title/Abstract[All Fields] OR

(("family"[MeSH Terms] OR "family"[All Fields]) AND distress[All Fields])) AND

Title/Abstract[All Fields] OR (Social[All Fields] AND distress[All Fields])) AND

Title/Abstract[All Fields] OR ("alcoholism"[MeSH Terms] OR "alcoholism"[All Fields] OR

("alcohol"[All Fields] AND "abuse"[All Fields]) OR "alcohol abuse"[All Fields])) AND

Title/Abstract[All Fields] OR ("substance-related disorders"[MeSH Terms] OR

("substance-related"[All Fields] AND "disorders"[All Fields]) OR "substance-related

disorders"[All Fields] OR ("drug"[All Fields] AND "abuse"[All Fields]) OR "drug abuse"[All

Fields])) AND Title/Abstract[All Fields] OR ("hostility"[MeSH Terms] OR "hostility"[All

Fields])) NOT ("patients"[MeSH Terms] OR "patients"[All Fields]) AND

("2005/03/08"[PDat] : "2015/03/05"[PDat])

Appendix B2

Item level quality ratings for 25 articles included in a systematic review of embedded student counselling between 2005-2015, split by quality rater

	Reporting (13)												Validity (4)				Bias (7)							Confounding (6)						Power (2)	
Item	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	Total
Max score	1	1	1	1	1	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	32
Austenfeld (R1)	1	1	1	1	1	1	0	1	0	1	0	0	1	1	1	0	1	1	1	1	1	1	1	1	0	1	0	1	0	2	*23*
Beintner (R1)	*1*	*1*	*1*	*1*	*0*	*0*	*0*	*1*	*1*	*0*	*1*	*1*	*0*	*0*	*1*	*0*	*0*	*0*	*0*	*0*	*1*	*0*	*1*	*0*	*0*	*1*	*0*	*1*	*0*	*0*	*13*
Beintner (R2)	*1*	*1*	*1*	*0*	*1*	*0*	*0*	*1*	*1*	*0*	*1*	*1*	*1*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*1*	*0*	*1*	*0*	*0*	*0*	*0*	*1*	*1*	*0*	*13*
Chung (R1)	1	1	1	1	0	1	0	0	0	0	0	1	1	1	0	1	1	0	0	0	0	0	0	0	0	0	0	0	1	0	11
Efstathiou (R1)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
Geisner (R1)	1	1	1	1	1	0	0	1	0	0	1	0	1	0	1	1	0	1	0	0	0	0	0	1	1	1	1	0	1	0	16
Geisner (R2)	*1*	*1*	*1*	*1*	*1*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*0*	*0*	*1*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*1*	*1*	*1*	*0*	*0*	*1*	*0*	*13*
Kass (R1)	1	1	1	1	1	1	1	1	1	1	0	0	0	0	0	1	1	1	1	1	0	0	1	1	1	1	1	1	1	1	23
Kass (R2)	*1*	*1*	*1*	*1*	*1*	*1*	*1*	*1*	*1*	*0*	*1*	*1*	*1*	*0*	*0*	*1*	*1*	*1*	*1*	*1*	*1*	*0*	*1*	*1*	*1*	*1*	*0*	*0*	*1*	*0*	*23*
Lee (R1)	1	1	1	1	0	1	1	0	1	1	0	0	1	0	0	0	0	0	0	0	1	1	1	1	0	0	0	1	0	0	*14*
Lee (R2)	*1*	*1*	*1*	*1*	*1*	*1*	*1*	*1*	*0*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*0*	*0*	*0*	*1*	*1*	*1*	*1*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*15*
Locklard (R1)	1	1	1	0	1	1	1	0	1	1	0	0	1	0	0	1	0	1	0	1	1	1	0	0	0	0	0	0	0	0	14
Mailey (R1)	1	1	1	1	1	0	1	1	1	0	0	0	1	1	1	0	0	1	1	1	1	1	1	0	1	1	0	1	1	1	22
Margrove (R1)	0	1	1	1	0	1	1	0	1	1	0	0	1	0	0	1	0	1	0	1	1	1	0	0	0	0	0	0	0	0	13
McVey (R1)	1	1	1	1	0	1	1	0	1	0	1	1	0	0	1	1	1	1	0	1	1	1	0	0	1	0	1	1	1	1	21
Meaney (R1)	1	1	1	1	1	1	1	1	0	0	1	1	1	0	0	1	0	0	0	1	1	1	1	0	1	0	0	0	1	0	18
Meaney (R2)	*1*	*1*	*1*	*1*	*1*	*1*	*0*	*1*	*0*	*0*	*1*	*1*	*1*	*0*	*1*	*1*	*0*	*0*	*0*	*0*	*1*	*1*	*1*	*1*	*1*	*0*	*0*	*0*	*1*	*0*	*18*

Appendix B2 (cont'd)

Item level quality ratings for 25 articles included in a systematic review of embedded student counselling between 2005-2015, split by quality rater

Item	Reporting (13)												Validity (4)				Bias (7)							Confounding (6)						Power (2)	Total
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	
Max score	1	1	1	1	1	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	32
Pistorello (R1)	1	1	1	1	1	1	1	1	1	1	0	0	1	1	0	0	1	1	1	1	1	1	1	0	1	0	1	1	1	1	24
Reynolds (R1)	1	1	0	1	0	1	1	0	0	1	0	1	1	0	1	0	1	1	0	1	1	1	0	0	1	1	1	0	1	0	18
Richards (R1)	0	0	0	1	1	0	1	0	0	1	0	0	1	0	0	0	0	0	0	0	1	1	0	0	0	1	0	0	1	0	9
Richards (pilot R1)	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*0*	*0*	*0*	*0*	*1*	*1*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*1*	*1*	*1*	*0*	*0*	*0*	*0*	*1*	*9*
Richards (pilot R2)	*0*	*0*	*1*	*0*	*0*	*1*	*0*	*1*	*0*	*0*	*0*	*0*	*1*	*0*	*1*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*1*	*1*	*1*	*0*	*0*	*0*	*0*	*1*	*9*
Schleicher (R1)	1	1	1	1	0	1	1	0	0	1	1	1	1	1	1	1	1	1	1	1	1	0	1	0	0	1	0	0	1	1	22
Short (R1)	1	1	1	1	1	1	1	0	0	1	1	1	1	1	0	1	1	1	1	1	0	0	1	1	0	1	0	0	0	1	21
Stewert (R1)	1	1	1	1	0	1	1	0	0	1	1	0	1	0	0	1	0	1	0	1	1	0	0	0	0	0	0	0	0	0	13
Stice (R1)	1	1	1	1	0	1	1	0	1	1	0	0	1	0	0	0	1	1	1	1	1	1	1	1	0	1	1	0	1	2	22
Tatum (R1)	1	1	1	0	1	0	1	0	1	0	0	0	1	0	0	0	0	0	0	1	1	0	0	0	1	0	0	1	0	1	12
Taylor (R1)	0	1	1	1	0	1	1	0	1	1	1	0	1	0	0	1	1	1	0	0	1	1	1	1	0	1	1	1	1	1	21
Tilfors (R1)	1	0	1	0	1	1	0	1	1	1	0	1	1	1	0	0	0	1	1	1	0	1	1	1	1	1	1	1	0	1	21

Appendix C1

Application form and materials submitted to the research ethics committee for an online survey of embedded counselling services

RESEARCH ETHICS APPROVAL FORM

STAFF/POSTGRADUATE RESEARCH

<u>All</u> staff (including research staff) and postgraduate students conducting research in the Department of Psychology must complete this form before commencing their research. Empirical work must not begin until the Department Ethics Sub-Committee has approved the research.	
Postgraduate Name	Miss Emma L Broglia
Research Staff Name	
Staff Name	Professor M Barkham and Dr A Millings
Date Ethics Form submitted	05/12/2014
Proposed starting date of research	05/01/2015
Brief title of investigation (state if this application is for a single study or for a series of studies using the same methodology): A Survey Evaluation of Counselling Services in Further and Higher Education (FE/HE) in the UK. This is a single study application to employ an online survey to counsellors to evaluate FE/HE counselling services in the UK	
Aims/value of research: Research on the effectiveness of counselling in higher and further education (HE/FE) is lacking and it is essential to build an evidence base to develop these services. Although the demand for counselling continues to rise, low response rates and missing data have hindered the evaluation and development of these services across the UK. The current study will address these	

issues with the following aims: 1) Capture information on a large representative sample of counselling services in FE/HE institutions across the UK; 2) Explore the use of face-to-face therapy in conjunction with e-therapies and internet resources; 3) Merge new data with existing data from the BACP and subject to statistical modelling to identify factors which impact counselling services; 4) Scope interest of collaborators for a related feasibility trial aiming to assess the effectiveness of University counselling.

Proposed participants in research (Explain fully who the participants will be and how they will be recruited. If the study does <u>not</u> involves a Level 1 Psychology student sample, the information sheet provided to participants must be attached to this form. If the study involves animals, state none and go to final section on research involving animals). If the study does not involve human or animals, e.g., computer modelling, state none and go to signature(s): Unique web links will be emailed to members of the BACP Heads of University Counselling (HUC) mailing list who have previously opted to receive an annual survey from BACP. Contact information of the researchers will be provided at the start of the survey to allow participants to ask additional questions. Participants will be asked, but not required, to provide their contact information if they are willing to be contacted for future studies.

Brief description of methods and procedure (give reference to established method where appropriate): Questions have been developed from an existing survey sent out annually by the BACP Universities & Colleges (UC) division, and this survey will replace this predecessor, thus creating no additional burden on respondents. The BACP will be consulted to review the questions. The questions will address core areas of the counselling services including: staffing, usage, types of counselling services available, use of e-therapy and online resources, budgets and future

development. The survey will also ask participants to indicate their interest in

collaborating with related studies and to provide their contact details. The survey

will be created under the departmental license with Qualtrics

(https://qualtrics.com/) and unique web links will be sent to the email addresses

received from the BACP UC. The top banner will comprise the University of

Sheffield logo and also the BACP logo to highlight their sponsorship of the

research and evoke trust in potential responders. The survey will be developed to

be more user friendly than its predecessors, in response to feedback on previous

versions and to reduce the time burden of completion. Whilst participants will not

be directly incentivised for completing the survey, a report of findings, featuring a

section tailored to each individual service, will be shared amongst participating

institutions. Survey data will be compared to data from previous years' surveys

and explored to identify factors which negatively and positively impact on

counselling services in the UK, such as increases in demand and budget cuts. Data

will also be compared to a recent report capturing University counselling services

in the USA to explore similarities and differences between the two populations.

These results will feed into a number of related studies to aid the development of

a feasibility trial to assess the effectiveness of counselling in higher education.

Has it been established that the proposed methodology will produce data from

which meaningful conclusions can be drawn? It is anticipated that circulating a

user friendly online survey backed and endorsed by the BACP will allow data to be

captured on a large representative sample of UK FE/HE counselling services. As

the survey includes adapted questions from an existing survey it will replace the

original planned BACP survey and will be circulated at a time when potential

responders are expecting to be contacted. Both these factors should optimise the

response rate and reduce the risk of missing data. Employing an adapted version

of the original survey will also allow data to be linked with existing data and

explored longitudinally.

How will participants give informed consent to participate in the study? (Give

details, including details of procedures involving parental or guardian consent): The

online survey will open with a background information page featuring rationale for

the study along with the aims and benefits of taking part. Participants will be

informed that data will be kept confidential and that they have the right to

withdraw without reason at any point. Participants will be instructed on how to

withdraw a) from the study, and b) their data from analyses. Participants will also

be instructed that they may request for their institution to remain anonymous by

selecting "no" when prompted with the question: "Are you willing for your

institution's name to be shared with other participating institutions?" Contact

details of the researchers will be provided on this page to allow responders to ask

additional questions before they decide to participate. At the bottom of the page

participants will be asked to select "yes" if they consent to participate in the study.

Selecting "yes" will prompt the start of the survey, whilst selecting "no" will direct

them to a 'ok, thanks anyway for your interest' page.

Does the study involve any of the following ethical issues? (circle all that apply)

An intervention/treatment is being conducted (i.e. this is a clinical trial see University definition at: http://www.sheffield.ac.uk/ris/other/gov-ethics/clinicaltrials	*No*
Questionnaires touching on sensitive issues	*No*
Deception	*No*
A procedure that might cause distress - even inadvertently	*No*

Designs involving stressful situations	*No*
Possible breach of confidentiality	*No*
Invasion of privacy	*No*
Working with children	*No*
Working with disabled people The production of recorded media such as audio and/or video recordings?	*No* *No*

What procedures will be used to address these issues (e.g. debriefing, providing information/help, ensuring confidentiality is preserved). Please ensure that if your project is a clinical trial you complete monitoring and adverse incident forms and submit them to the Chair of the Ethics Committee as required. The committee may ask to see copies of relevant documents. There are no risks or concerns anticipated in this study. A debrief statement will be provided at the end of the survey to summarise the intentions of the study and thank participants for completing the survey. The contact details of the researchers will be provided again at the end of the survey in case participants have additional questions or would like to make a complaint.

IF YOUR EXPERIMENT INVOLVES LEVEL 1 PSYCHOLOGY STUDENTS: Please provide a description of your experiment that can be given to participants once they have taken part. Note that this description should include full account of the aims and method that you used (min. 150 words) – students will need this information for their PSY104 assessment. N/A

What measures will be put in place to ensure confidentiality of personal data, where appropriate? After download from Qualtrics, data will be kept confidentially and only accessible to the research team. Where appropriate, data will be

anonymised at the earliest opportunity (after download from Qualtrics). Data will be analysed and disseminated for scientific purposes only.
Will financial / in kind payments (other than reasonable expenses and compensation for time) be offered to participants? (Indicate how much and on what basis this has been decided) Participants will not be incentivised financially, but all participating institutions will receive a report detailing findings.

<u>Research Involving Animals</u>

Under whose personal licence will the work be conducted?
Under which project licence will the work be conducted?
If the work is not covered by a licence (e.g., because it involves insects) please give justification

| X |

<u>I confirm that I have read the current version of the University of Sheffield 'Ethics Policy Governing Research Involving Human Participants, Personal Data and Human Tissue', as shown on the University's research ethics website at:</u>

www.sheffield.ac.uk/ris/other/gov-ethics/ethicspolicy

Signed Declaration

Title of Research Project: *A Survey Evaluation of Counselling Services in Further and Higher Education in the UK*

I confirm my responsibility to deliver the research project in accordance with the University of Sheffield's policies and procedures, which include the University's '*Financial Regulations*', '*Good Research Practice Standards*' and the '*Ethics Policy Governing Research Involving Human Participants, Personal Data and Human Tissue*'

(Ethics Policy) and, where externally funded, with the terms and conditions of the

research funder.

In signing this research ethics application form I am also confirming that:

- The form is accurate to the best of my knowledge and belief.

- The project will abide by the University's Ethics Policy.

- There is no potential material interest that may, or may appear to, impair the

   independence and objectivity of researchers conducting this project.

Subject to the research being approved, I undertake to adhere to the project protocol

without unagreed deviation and to comply with any conditions set out in the letter from

the University ethics reviewers notifying me of this. I undertake to inform the ethics

reviewers of significant changes to the protocol (by contacting my academic

department's Ethics Administrator in the first instance).

I am aware of my responsibility to be up to date and comply with the requirements of

the law and relevant guidelines relating to security and confidentiality of personal data,

including the need to register when necessary with the appropriate Data Protection

Officer (within the University the Data Protection Officer is based in CiCS). I understand

that the project, including research records and data, may be subject to inspection for

audit purposes, if required in future. I understand that personal data about me as a

researcher in this form will be held by those involved in the ethics review procedure

(e.g. the Ethics Administrator and/or ethics reviewers) and that this will be managed

according to Data Protection Act principles.

If this is an application for a 'generic' project all the individual projects that fit under the

generic project are compatible with this application. I have read the BPS ethical

guidelines for research and I am satisfied that all ethical issues have been identified and

that satisfactory procedures are in place to deal with those issues in this research. I will

abide by University Health and Safety Regulations

(http://www.shef.ac.uk/safety/cop/part1/index.html) including the codes of practice

designed to ensure the safety of researchers working away from University premises. I

understand that this project cannot be submitted for ethics approval in more than one

department, and that if I wish to appeal against the decision made, this must be done

through the original department.

Name of the Principal Investigator (or the name of the Supervisor if this is a postgraduate

researcher project): Professor M Barkham

If this is a postgraduate project insert the student's name: Miss E Broglia

Signature of Principal Investigator (or the Supervisor):

Date: 5th December 2014

EXPERIMENTER SAFETY

This form must be completed by all students prior to starting their projects and must

be submitted at the same time as they submit an ethics form. No research must be

conducted until after the Department has considered both the Ethics form and the

Experimenter Safety form and given permission for the research to go ahead.

Background: Students in the Department of Psychology will frequently be involved in

projects that involve experimenters collecting data from participants. For example,

these projects might include collecting data for laboratory classes in taught modules, for

Level 3 dissertations, or for postgraduate research. The participants could include, for

example, other Psychology students, students in other Departments, friends and

acquaintances outside the Department, or members of the public. The research might

take place on University premises, or in other organisations (e.g. schools, hospitals,

companies), or might be conducted in public places. Supervisors and students must

consider the potential risks to experimenters in any empirical research. Supervisors and

students must be familiar with the guidance and advice provided by Safety Services

about conducting research, especially when the experimenter is working alone. See

http://www.shef.ac.uk/safety/guidance/loneworking.html

Please complete the following (please answer all questions that are relevant):

Will the project be conducted on Sheffield University premises?

YES – data collection will be conducted online via Qualtrics

Will the experimenter conduct research on other <u>premises</u>?   NO

If YES please specify by ticking box(es) below and give details:

Other University premises   ☐ where?..

School/Educational premises   ☐ where?..

Hospital/Clinic   ☐ where?..

Company/Business   ☐ where?..

Prison/Offenders institution   ☐ where?..

Social/bar premises   ☐ where?..

Private houses/flats etc.   ☐ where?..

Other premises ☐ where?..

Will the experimenter conduct research in other <u>places</u>?   NO

If YES please specify by ticking box(es) below and give details

Camps/playgrounds   ☐ where?..

Sports facilities ☐ where?..

Public spaces/malls   ☐ where?..

Streets ☐ where?..

Other ☐ where?..

Might the participants pose any risk to the experimenter?   NO
Where necessary, please describe below the measures that have been put in place to ensure the safety of the experimenter. Please refer to the Safety Services web pages for examples of appropriate measures. This study employs an online survey only and there are no risks or concerns anticipated.

Please note. Undergraduate experimenters must never work alone in the following environments: participants' homes, social/bar premises, or any other environment that may pose a risk to the experimenter.

Students should tick the following boxes and sign below:

✔ I have read the relevant Safety Services information.

✔ I have fully considered any potential risks that the proposed experiment might have.

✔ I will inform my supervisor/the Department immediately should the research alter in such a way that the level of risk becomes greater than stated above.

✔ If, at any time, I am concerned about the risks entailed in my research I will stop the research and discuss my concerns with my supervisor.

Signed Student: **Date:** 5th December 2014

Supervisors should tick the following boxes and sign below:

✔ I have read the relevant Safety Services information.

✔ I have discussed any potential risks with the student.

✔ I am satisfied that measures outlined above are the most appropriate ones to minimise risk to the experimenter.

Appendix C1 (cont'd)

List of survey questions and definitions used in survey

Survey Evaluation of Counselling Services in Further and Higher Education 2013/14

The British Association for Counselling and Psychotherapy (BACP) has combined efforts with the University of Sheffield to build a robust research evidence base to support the effectiveness of student counselling services.   To mark this new initiative, the usual BACP-UC annual survey has been replaced with an updated version with additional aims to address recent incentives for service development. The aims of the survey are: 1) Capture information on counselling services in FE/HE in the UK; 2) Explore the use of face-to-face therapy in conjunction with e-therapy/online resources; 3) Identify factors which impact on counselling services to advise development; 4) Seek expression of interest from potential collaborators for a related feasibility trial.

Confidentiality

All data collected will be confidential and used for scientific purposes only. You will be asked to provide your institution's name, but you may choose to withhold this information. If you do provide the name of your institution, your details will NOT be available to others. However, you WILL be able to see overall anonymised data to see how your service compares to others. Data will also contribute to a feasibility trial aiming to evaluate the effectiveness of counselling services in further and higher Education. You have the right to withdraw at any stage without reason, by simply closing your browser. If you wish to withdraw the data you have submitted up to that point, you will need to contact the research team (details below) to request this. This study has received ethical approval from the University of Sheffield.

Completing the survey

The survey will remain live for 2 weeks and you will be prompted when the closing date

is approaching. Please be mindful that the survey session will time out if the page is

inactive for more than 10 minutes. If you would like to save and complete the survey

across multiple sittings please provide your email below and we will email you a unique

link for the survey. If you have already submitted your email to receive a unique link,

please refer to the link in your email rather than continuing this version of the survey. If

you do not have a unique link in your email you may contact the research team to

request another email prompt (see below). We acknowledge that certain questions may

be difficult to answer and we appreciate your patience. If you would like to provide

suggestions to improve the survey further please provide feedback in the comment box

at the end.

To request for the option to save and return to the survey across multiple sittings,

please provide your email below. Otherwise you may enter the survey below and

complete the survey in one sitting.

Do you consent to take part in the above study? (Please select 'Yes' to begin the

survey) Yes/No   *Logic: If No Is Selected, Then Skip To End of Survey*

The questions in this survey refer to the academic year 2013-2014, unless otherwise

stated. Thank you for your time and cooperation for completing this survey.

1. Name of your institution: (Optional)

If you provide your name, your details will NOT be available to others. However, you

WILL be able to see the complete anonymised dataset and see how your service

compares to the data of all the others.

2. Is your institution part of the Further Education or Higher Education sector?

- Further Education / Higher Education / Combined, predominately FE /

   Combined, predominately HE

3. Which group does your institution belong to?

- Million + / Russell Group / University Alliance / Ukadia / Other (please specify)

4. How many years has your institution offered a counselling service?

5. For whom does your institution provide counselling services? (select all which apply)

Students / Staff

5b. Are your counselling services for students and staff run within the same service or

separate services?

Same service / Separate service / Not applicable

5c. If you outsourced staff counselling services in 2013/14, please could you provide a

brief description of the services that were offered:

6. In total, how many students were registered at your institution in 2013-14? (Not

including partner/franchise/satellite institutions)

7. If you provided counselling services to partner/franchise/satellite institutions in

2013/14, how many students were registered and had access to the counselling services?

- Number of students: / Not applicable:

8. What was the full-time equivalent (FTE) of paid counselling/therapeutic staff for 2013-

14? Please note that a total FTE is sufficient if the breakdown doesn't compliment your

service; you may also elaborate in the comment box below if you choose to

High intensity work (counselling, psychotherapy, CBT, therapeutic group work FTE:

Low intensity work (Psychological Wellbeing Practitioner, wellbeing workers) FTE:

Group work (psychoeducation, healthy campus, education, low intensity groups) FTE:

Total FTE:

8b. Additional comments regarding full-time equivalent paid staff (optional)

9. What were the total counselling/therapeutic staffing and non-staffing* budgets for

2013-14? *non-staffing budgets may include training, facilities, software etc

- Staffing budget: Non-staffing budget:

10. Did you use unpaid/volunteer/trainee counsellors during 2013-14?

- Yes / No

10b. What was the full-time equivalent* of unpaid staff?

*Therapeutic contact including supervision is assumed to be 25 hours per FTE staff

member. To calculate the contribution of volunteers (including their supervision) is: 3

hours = 0.12; 3.5 hours = 0.14; 4 hours = 0.16; 4.5 hours = 0.18; 5 hours = 0.20; 5.5

hours = 0.22; 25 hour week = 1 FTE. Please note that a total is sufficient if the

breakdown provided doesn't compliment your service

- Provide counselling (paid FTE):

- Provide CBT (paid FTE):

- Provide other psychotherapy (paid FTE):

- Total (paid FTE):

11. What was the full time equivalent of the Mental Health Advisor(s)* in your institution during 2013-14? *for example someone whose specific role is to assess the impact of mental health needs on academic ability and provide information about mental health issues and the services/support available

- FTE of MHA: Did not use MHA:

11b. Comments regarding your Mental Health Advisor: (Optional)

11c. Who managed the Mental Health Advisor(s)* in your institution in 2013-14? *For example, counselling service or disability service

12. How many students and staff members used your counselling services, and attended at least one session in 2013-14? (including drop-in, self-referral and excluding partner institutions). High intensity = Counselling, CBT, psychotherapy, ongoing psychotherapeutic groups. Low intensity = One-off workshop, short series, short group work sessions, psychoeducation

Students/staff:

- High intensity: Low intensity: Assessment only: Total:

13. In the boxes below, please indicate how many students and staff members used your services and attended at least one session across the last 3 years: (including drop-in, self-referral and excluding partner institutions)

Students/staff: 2013-2014:   2012-2013:   2011-2012:

14. Did you offer assessment in 2013-14?

- Students/staff: Yes / No

15. Please specify which outcome measure(s) were collected routinely, by the majority of

practitioners in 2013-2014:

15b. Please could you describe any problems you experienced gathering, analysing or

using outcome data in 2013-2014:

16. At which time points did you administer outcome measures in 2013-2014?

- One application (Pre): Yes / No

- Every session: Yes / No

- Post (when possible): Yes / No

17. What data did you gather to monitor SERVICE usage* in 2013-2014?

*for example, completion rate, proportion of cancelled sessions, approx % etc

18. What were the modal (most common) and maximum number of attended sessions in

2013-2014?

Students/staff:

- Most common number of attended sessions: Maximum number:

19. How many non-attended* sessions were there in 2013-14? *Defined as sessions in

which the student of staff member did not attend or cancelled after referral. If exact

numbers are unknown, please provide an approximate percentage of clients who did

not attend sessions

- Students/staff: Non-attended in 2013-14:   Approximate DNA %:

20. In the boxes below, please indicate the mean waiting periods for assessment (if offered) and ongoing sessions in 2013-2014: (not including emergency/crisis counselling)

If the assessment is combined with the first support session, please provide the waiting period for the first session after first contact in the assessment fields

- Mean waiting period for assessment after first contact (students/staff):

- Mean waiting period for ongoing sessions (students/staff):

21. In 2013-2014, how rapidly* could clients routinely access a counseller if needed?

*For quick access to counsellors even if emergency services are not necessarily offered

22. In 2013-2014, did you have access to a local primary and secondary mental health service to liaise regarding students?   Yes / No

22b. Please could you describe the arrangements you had with the local primary and secondary mental health service in 2013-2014:

22c. If you intend* to plan care between local mental health services and institutional support, please describe the arrangements: *or if local MH services were put in place after the 2013-2014 period

23. In the boxes below, please indicate the type of psychoeducational workshops you offered (if any) in 2013-2014: For example; stress management groups, procrastination groups, confidence building workshops, counselling service 'open day'

- Type of workshop held in 2013/14 (list ~10):

- Number of corresponding workshops held in 2013/14:

23b. If you would like to provide additional comments about the psychoeducational

groups your service held in 2013-2014, please comment in the box below: (Optional)

24. How many students and staff members attended the psychoeducational workshops

(or other group types) in 2013-14?

- Total in 2013/14 (students/staff):

25. Please indicate which forms of support your institution offered in 2013-2014, which

forms of support your service offers currently and which forms of support you would like

to offer out of the following:

Answer for "offered in 2013/14", "currently offer", and "would like to offer" for the

following:

- Face-to-face:

- Group therapies:

- Peer-led support:

- Self-help book:

- Self-help resources online:

- Online or e-therapies:

- Mobile phone apps for mental health:

26. What other forms of support do you offer?

27. What other forms of support would you like to offer?

This final section aims to capture information about a range of online self-help resources or online support communities your service offered in 2013/14 and whether they are likely to be incorporated in the near future.

28. Out of the following online resources, please indicate what your service already offers and what you would like to offer: If you would like to provide additional comments about online resources and e-therapies, there is a comment box at the end of this section. Answer for "offered in 2013/14", "currently offer", and "would like to offer" for the following:

- Informational websites about staying mentally healthy (developed in-house):

- Direct visitors to the institution's website which redirects to trusted external websites:

- Pay for a commercial, interactive online self-help programme / e-therapy:

- Developed own interactive online self-help programme /e-therapy:

- Pay for commercially available access to support online community:

- Use freely available access to support online community:

- Developed in-house supportive online community:

- Provide counselling by email or online chat:

- Provide counselling by telephone or video calling:

- Use or recommend mobile phone apps for mental health:

29. We'd like to know what you think about online resources and e-therapies in general. Please rate the extent to which you agree with each item:

Answer format: Strongly disagree; disagree; neutral; agree; strongly agree

- Students feel like they aren't getting 'real' therapy if we suggest online self-help

- Students tend to want face-to-face counselling above all else

- Motivation is a big problem for those engaging in online self-help

- We can't tell whether students use the online resources we provide

- If I suggest to use an online programme, I would like to track my client's use/progress

- We can't tell whether online resources help

- We'd like to try online resources, but are limited by costs

- Interactive online resources for mental health are extremely variable in quality

- We'd like to use online self-help more, but I would like advice on how to implement it

- I know that we need to better support online resources, but it's difficult to know how

- We have a great offering of online resources and I'm happy with the way we support it

30. If you could make one change to your counselling service and money were no object, what would it be?

Would you be willing to be contacted for a telephone/skype interview to discuss your counselling service in more detail? Yes / No

If you would like to be contacted for a telephone interview or for collaborating with the related feasibility trial, please provide your contact details below:

- Title: Name: Position at institution: Time at institution (years/months):

- Email: Contact number:

Ethical approval letter for the online survey and telephone interviews comparing service data across student counselling services in HE, FE, and SFCs (email)

From: **Psychology Research Ethics Application Management**

System <no_reply@psychologyresearchethicsapplicationmanagementsystem>

Date: 17 December 2014 at 13:58

Subject: Approval of your research proposal

To: A.Millings@sheffield.ac.uk

Your submission to the Department of Psychology Ethics Sub-Committee (DESC) entitled

"A Survey Evaluation of Counselling Services in Further and Higher Education (FE/HE) in

the UK" has now been reviewed. The committee believed that your methods and

procedures conformed to University and BPS Guidelines.

I am therefore pleased to inform you that the ethics of your research are approved. You

may now commence the empirical work.

Yours sincerely,

Dr Tom Webb

Chair, DESC

Appendix D1

Application form and materials submitted to the research ethics committee for a pilot study exploring the acceptability, feasibility, and initial psychometric properties of the CCAPS clinical measure

RESEARCH ETHICS APPROVAL FORM

STAFF/POSTGRADUATE RESEARCH

<u>All</u> staff (including research staff) and postgraduate students conducting research in the Department of Psychology must complete this form before commencing their research. Empirical work must not begin until the Department Ethics Sub-Committee has approved the research.	
Postgraduate Name	Miss Emma L Broglia
Research Staff Name	
Staff Name	Professor M Barkham; Dr A Millings
Date Ethics Form submitted	08/04/2015
Proposed starting date of research	13/04/2015

Brief title of investigation (state if this application is for a single study or for a series of studies using the same methodology): An opportunistic service development comparison of CORE-10 and CCAPS outcome measures in UK university counselling services. This is a single study application to compare two well-known clinical outcome measures as part of planned service development in university counselling centres.
Aims/value of research: University counselling services vary in the process by which they routinely collect clinical outcome data from their clients and this has prevented shared practice. There are a number of tools available to routinely measure clinical outcomes in students, but there are currently no guidelines to

facilitate informed decision making in selecting a clinical outcome measure. For many years the majority of UK university counselling services have administered the Clinical Outcomes in Routine Evaluation (either the CORE-OM or CORE-10) assessment which is commonly used across many counselling sectors. However, in recent years a new outcome measure has been developed on American Universities to specifically monitor clinical outcomes in university students – the Counselling Centre Assessment of Psychological Symptoms (CCAPS). The CCAPS is the first measure designed specifically for the student population and for this reason a number of UK universities have started to implement CCAPS. However, CCAPS is yet to be validated in a UK sample and university counselling services have expressed a concern for differences in how CORE and CCAPS measure risk in UK students. The proposed application intends to address these concerns with the following aims: 1) Collaborate with university counselling services using or intending to use CCAPS, through a recently established practice-research network; 2) Facilitate planned service development in university counselling services intending to administer CCAPS alongside CORE-10; 3) Analyse anonymised data on CORE-10 and CCAPS measures from collaborating counselling services to explore the construct of the two outcome measures; 4) Validate CCAPS in an UK student sample.

Proposed participants in research (Explain fully who the participants will be and how they will be recruited. If the study does not involves a Level 1 Psychology student sample, the information sheet provided to participants must be attached to this form. If the study involves animals, state none and go to final section on research involving animals). If the study does not involve human or animals, e.g., computer modelling, state none and go to signature(s): A practice-research network was recently established between heads of university counselling services and the researchers named in this application. Members of the network are planning to

administer CCAPS alongside CORE to allow a direct comparison of how the tools measure clinical outcome and to aid informed decision making in service. For the purposes of the proposed application, members of the network will be emailed guidelines for implementing CCAPS and CORE-10 to ensure standardisation across the counselling centres. The heads of counselling at each centre will encourage their counselling staff to employ CCAPS and CORE-10 during a set period of planned development. Whilst the period of planned development will vary across counselling centres, it is anticipated to take place from April 13 2015.

Brief description of methods and procedure (give reference to established method where appropriate): Both CCAPS and CORE are validated outcome measures used within the university counselling domain and the intended counselling centres are familiar with both tools. The reporting forms are already available; require no additional cost, and run on the software already being used by the intended counselling centres. The novel component of this planned service development is administering both tools – rather than choosing one – to allow direct comparison and inform decision making for choosing an outcome measure. A set of guidelines for administering CCAPS and CORE-10 measures will be developed and circulated to heads of counselling to review.

The guidelines will detail how to upload the relevant forms and the time points at which the forms should be administered. All participating counselling centres intend to administer CORE-10 and CCAPS from April 2015. Any member of counselling staff (including trainee/unpaid/volunteer) is able to administer CORE-10 and CCAPS if they choose to during this time. Where feasible, both measures will be administered at the start of every session, for new clients only. The order of administration will be randomised across counselling centres, counterbalanced for centre size, and set-up in advance on the computer system. The randomisation

table is provided in the appendix item 1.1. Instructions for ordering the forms on

the computer system will be detailed in the guide (appendix 1.2). CCAPS is already

administered by members within the network and the only anticipated change will

be administering an additional 10 questions from CORE-10; a tool all centres used

prior to using CCAPS. The short version of CORE has been chosen for this purpose to

minimise the burden of students attending counselling and to avoid disruption in

the usual running of the service.

Students will complete the forms on an iPad in reception whilst waiting for their

counselling session – a process already used at the intended counselling centres.

During the service development phase, an A5 information poster will be attached

to the cover of the iPads to explain to students that they may be randomly selected

to complete CORE-10 in addition to their usual assessment forms (see appendix

1.5) as part of the service development. The purpose of this is to provide students

with the opportunity to opt-out, and to also highlight the new collaborative

initiative between the university counselling centres.

Heads of university counselling will anonymise and share CORE/CCAPS data with the

research team to be merged with anonymised data from other university

counselling services. This ethics application is to apply for approval to analyse the

anonymised data to be provided by the counselling services. Analyses will explore

differences across the two measures and to validate the use of CCAPS in a UK

sample. The findings will be shared with participating services and will also

contribute to a related feasibility trial exploring outcome measures in university

counselling.

Has it been established that the proposed methodology will produce data from which

meaningful conclusions can be drawn? Strong links have been established between

the intended counselling centres and the researchers named in this application; as

part of the newly formed practice-research network. Members within the network already intend to administer CCAPS with CORE and possess the relevant facilities to do so. The researchers in the proposed application will be a focal point for the counselling centres to liaise with and to advise where necessary. Based on the number, size and time of data collection across the intended counselling centres, it is anticipated that data from up to 400 students can be gathered. A sample of 400 students on CCAPS-34 and CORE-10 will support confirmatory factor analysis (CFA) to test the constructs of the two tools.

How will participants give informed consent to participate in the study? (Give details, including details of procedures involving parental or guardian consent): Analysis of anonymised clinical outcome measures within counselling services has been standard practice for a number of years, and is widely seen within the sector and outside in NHS therapy services as being part of good practice. For this purpose, it is common practice for the existing contract between university counselling services and clients using the service to specify that information gathered by the service may be used for research purposes in anonymised form. Participants are at liberty to decline - as they are at liberty to decline to complete the standard service assessment forms. Declining will not impact on the service they receive.

The methods stated in this application refer to planned service development of university counselling services and researchers will only have access to anonymised data for the purposes of service evaluation. The Heads of University counselling centres have already established collaboration through the practice-research network and already intend to implement the methods proposed in this application as part of their service development work. Therefore, the researchers will not have any direct contact with participants from whom to register consent. Information on the service development will be printed on the covers of iPads given to students in

the counselling centres when they complete their usual assessments. The information will inform students to speak to the receptionist if they choose to opt-out of the service development.	
Does the study involve any of the following ethical issues? (circle all that apply)	
An intervention/treatment is being conducted (i.e. this is a clinical trial see University definition at: http://www.sheffield.ac.uk/ris/other/gov-ethics/clinicaltrials	*No*
Questionnaires touching on sensitive issues	*Yes*
Deception	*No*
A procedure that might cause distress - even inadvertently	*No*
Designs involving stressful situations	*No*
Possible breach of confidentiality	*No*
Invasion of privacy	*No*
Working with children	*No*
Working with disabled people	*No*
The production of recorded media such as audio and/or video recordings?	*No*
What procedures will be used to address these issues (e.g. debriefing, providing information/help, ensuring confidentiality is preserved). Please ensure that if your project is a clinical trial you complete monitoring and adverse incident forms and submit them to the Chair of the Ethics Committee as required. The committee may ask to see copies of relevant documents. CCAPS is already employed by the intended University Counselling Services and the only anticipated change will be administering an additional 10 questions from CORE-10. CORE-OM, a longer version of this outcome measure, was administered to clients at University	

Counselling Services for a number of years prior to the introduction of CCAPS in

September 2013. There is little to no potential psychological harm/distress

anticipated from this intended service development.

The 10 additional questions address topics of mental health which may be regarded

as a sensitive issue, but the questions are in-line with the questions already asked

in standard care and participants will be in the best place to deal with any

emotional consequences they experience from answering the questions. Clients will

be provided with information on the planned service development; an A5

information poster on the cover of the iPad in which they complete the standard

service forms. This will provide an opportunity to ask questions and to decline from

completing any of the forms – in line with standard practice. The information poser

will highlight to clients that declining will not impact their standard of care. All data

will be anonymised before being shared with researchers for analysis.

IF YOUR EXPERIMENT INVOLVES LEVEL 1 PSYCHOLOGY STUDENTS: Please provide a

description of your experiment that can be given to participants once they have

taken part. Note that this description should include full account of the aims and

method that you used (min. 150 words) – students will need this information for their

PSY104 assessment. Please ensure that the reference provided is available through

the University of Sheffield library. N/A

What measures will be put in place to ensure confidentiality of personal data, where

appropriate? Heads of university counselling services will anonymise data before

sharing it with the research team to merge with anonymised data from other

university counselling centres. The research team will not have access to any

personal identifiable data from clients attending any of the counselling centres.

Will financial / in kind payments (other than reasonable expenses and

compensation for time) be offered to participants? (Indicate how much and on

what basis this has been decided). This project is part of planned service

development and will not incentivise participants directly; however, heads of

university counselling services will receive an overall report detailing the evaluation

of the two outcome measures.

Research Involving Animals

Under whose personal licence will the work be conducted?	
Under which project licence will the work be conducted?	
If the work is not covered by a licence (e.g., because it involves insects) please give justification	

| X |

I confirm that I have read the current version of the University of Sheffield

'Ethics Policy Governing Research Involving Human Participants, Personal Data and

Human Tissue', as shown on the University's research ethics website at:

www.sheffield.ac.uk/ris/other/gov-ethics/ethicspolicy

Signed Declaration

Title of Research Project: *A Service Development Comparison of CORE and CCAPS*

Outcome Measures in UK University Counselling Services

I confirm my responsibility to deliver the research project in accordance with the

University of Sheffield's policies and procedures, which include the University's

'*Financial Regulations*', '*Good Research Practice Standards'* and the '*Ethics Policy*

Governing Research Involving Human Participants, Personal Data and Human Tissue'

(Ethics Policy) and, where externally funded, with the terms and conditions of the

research funder. In signing this research ethics application form I am also confirming

that:

- The form is accurate to the best of my knowledge and belief.

- The project will abide by the University's Ethics Policy.

- There is no potential material interest that may, or may appear to, impair the

  independence and objectivity of researchers conducting this project.

Subject to the research being approved, I undertake to adhere to the project protocol

without unagreed deviation and to comply with any conditions set out in the letter from

the University ethics reviewers notifying me of this. I undertake to inform the ethics

reviewers of significant changes to the protocol (by contacting my academic

department's Ethics Administrator in the first instance).

I am aware of my responsibility to be up to date and comply with the requirements of

the law and relevant guidelines relating to security and confidentiality of personal data,

including the need to register when necessary with the appropriate Data Protection

Officer (within the University the Data Protection Officer is based in CiCS).

I understand that the project, including research records and data, may be subject to

inspection for audit purposes, if required in future. I understand that personal data

about me as a researcher in this form will be held by those involved in the ethics review

procedure (e.g. the Ethics Administrator and/or ethics reviewers) and that this will be

managed according to Data Protection Act principles. If this is an application for a

'generic' project all the individual projects that fit under the generic project are

compatible with this application.

I have read the BPS ethical guidelines for research and I am satisfied that all ethical

issues have been identified and that satisfactory procedures are in place to deal with

those issues in this research. I will abide by University Health and Safety Regulations

(http://www.shef.ac.uk/safety/cop/part1/index.html) including the codes of practice

designed to ensure the safety of researchers working away from University premises.

I understand that this project cannot be submitted for ethics approval in more than one

department, and that if I wish to appeal against the decision made, this must be done

through the original department.

Name of the Principal Investigator (or the name of the Supervisor if this is a postgraduate

researcher project): Professor M Barkham

If this is a postgraduate project insert the student's name here: Miss E Broglia

Signature of Principal Investigator (or the Supervisor):

Date: 27th March 2015

EXPERIMENTER SAFETY

This form must be completed by all students prior to starting their projects and

must be submitted at the same time as they submit an ethics form. No research

must be conducted until after the Department has considered both the Ethics

form and the Experimenter Safety form and given permission for the research to

go ahead.

Students in the Department of Psychology will frequently be involved in projects that involve experimenters collecting data from participants. For example, these projects might include collecting data for laboratory classes in taught modules, for Level 3 dissertations, or for postgraduate research. The participants could include, for example, other Psychology students, students in other Departments, friends and acquaintances outside the Department, or members of the public. The research might take place on University premises, or in other organisations (e.g. schools, hospitals, companies), or might be conducted in public places. Supervisors and students must consider the potential risks to experimenters in any empirical research. Supervisors and students must be familiar with the guidance and advice provided by Safety Services about conducting research, especially when the experimenter is working alone.

See http://www.shef.ac.uk/safety/guidance/loneworking.html

Please complete the following (please answer all questions that are relevant):

Will the project be conducted on Sheffield University premises?   YES – anonymised data will be provided by external university counselling centres and data will be analysed by the research team at Sheffield University

Will the experimenter conduct research on other <u>premises</u>?   NO

If YES please specify by ticking box(es) below and give details:

Other University premises   ☐ where?..

School/Educational premises   ☐ where?..

Hospital/Clinic   ☐ where?..

Company/Business   ☐ where?..

Prison/Offenders institution   ☐ where?..

Social/bar premises   ☐ where?...

Private houses/flats etc.   ☐ where?...

Other premises ☐ where?...

Will the experimenter conduct research in other <u>places</u>?   NO

If YES please specify by ticking box(es) below and give details

Camps/playgrounds   ☐ where?...

Sports facilities ☐ where?...

Public spaces/malls   ☐ where?...

Streets ☐ where?...

Other   ☐ where?...

Might the participants pose any risk to the experimenter?   NO
Where necessary, please describe below the measures that have been put in place to ensure the safety of the experimenter. Please refer to the Safety Services web pages for examples of appropriate measures. This study involves analysis of anonymised service data only and there are no risks or concerns anticipated.

Please note. Undergraduate experimenters must never work alone in the following environments: participants' homes, social/bar premises, or any other environment that may pose a risk to the experimenter.

Students should tick the following boxes and sign below:

- ✔ I have read the relevant Safety Services information.

- ✔ I have fully considered any potential risks that the proposed experiment might have.

✔ I will inform my supervisor/the Department immediately should the research alter in

such a way that the level of risk becomes greater than stated above.

✔ If, at any time, I am concerned about the risks entailed in my research I will stop the

research and discuss my concerns with my supervisor.

Signed Student: **Date:** 27th March 2015

Supervisors should tick the following boxes and sign below:

✔ I have read the relevant Safety Services information.

✔ I have discussed any potential risks with the student.

✔ I am satisfied that measures outlined above are the most appropriate ones to

minimise risk to the experimenter.

Appendix D1 (cont'd) materials

Randomisation table:

Site Name	Site Number	Form_1	Form_2	Site size (approx. total student count)
University of Sheffield	1	CORE-10	CCAPS-34	26309
University of Keele	2	CCAPS-34	CORE-10	10154
University of Bangor	3	CORE-10	CCAPS-34	10460
University of Bradford	4	CCAPS-34	CORE-10	12000
University of Sussex	5	CORE-10	CCAPS-34	13000
Manchester Metropolitan University	6	CCAPS-34	CORE-10	32162

Sites have been counterbalanced by size across randomisation of the tools

Appendix D1 (cont'd) materials

A guide for administering CORE-10 and CCAPS-34 outcome measures in Titanium

Intentions and expected outcomes

The aim of this guide is to provide a standardised set of instructions for counselling centres intending to administer CORE-10 and CCAPS-34 outcome measures, side-by-side, during a period of planned service development. The proposed period to administer CORE-10 with CCAPS-34 commences in **April 2015**. For the purpose of this comparison, the CORE-10 form has been developed in Titanium© and instructions for importing the form are included in this guide.

At the end of the data collection period, data from all participating counselling services will be anonymised, collated and analysed for the following intentions: 1) Provide a direct comparison of CORE-10 and CCAPS outcome measures; 2) Explore similarities and differences between how the tools measure risk; 3) Validate CCAPS in a UK sample.

To fulfil the intentions stated above, it is expected that data from 400 students can be collected across participating sites during April-June 2015.

Why should I take part?

There is a unique opportunity to validate CCAPS in a UK sample by sharing anonymised data across UK University Counselling Services that are already administering CCAPS. To date it is not known how well CCAPS is able to detect risk in UK students and comparing CCAPS to CORE-10 will allow a direct comparison. In order to reduce the burden on clients attending counselling and to minimize service disruptions, the CORE-10 has been chosen to represent the CORE-OM. By administering CCAPS and CORE-10 for a brief period of time it is hoped that sufficient data will be collected without causing additional

and unnecessary burden. The research team at the University of Sheffield facilitating

this planned service development will perform all necessary analyses and will share

reports with participating centres.

Am I eligible to take part?

You are eligible if your counselling service meets the following criteria:

Your clients are students of higher or further education

Your computers run Titanium©

If you have questions regarding eligibility, please contact the research team (details

below)

Is this project safe?

Yes. Whilst these guidelines are intended to facilitate service development, the methods

have been approved by the Research Ethics Committee at the University of Sheffield

and are endorsed by the British Association for Counselling and Psychotherapy (BACP).

How will the identity of my clients be protected?

At the end of the agreed data collection period, you will be asked to anonymise your

clients' data with unique IDs; by following the instructions provided in this guide. No

personal identifiable data will be shared outside your counselling service. The research

team will not have access to any personal information from your clients or your staff. All

data will be anonymous.

Can I analyse the data myself?

Yes. You will be able to analyse your data as you see fit and you will be kept informed on

the progress of analysis on the combined dataset. You will be asked to share

anonymised data with the research team to allow data to be combined across all

participating counselling centres. All participating centres will be encouraged to

contribute to the development of the final report.

When do I administer CORE-10 and CCAPS-34?

From Monday 13th April 2015, all participating counselling centres will be encouraged to

administer CORE-10 and CCAPS-34. Any member of counselling staff (including

trainee/unpaid/volunteer) is able to administer CORE-10 and CCAPS-34 if they choose to

during this time. Where feasible, both CORE-10 and CCAPS-34 will be administered at

the start of every session, for **new** clients only. If your service already administers

CCAPS-64 on the first session, please still administer CORE-10 at this session. From

session 2 onwards, please administer CCAPS-34 with CORE-10. The order of

administration has been randomized across counselling centres and the allocation for

your counselling centre is detailed below:

> Name of counselling centre: ………………………………………………………..
> Please always administer (1) …………………… followed by (2) …………………….

How do I upload the CORE-10 form to Titanium?

The CORE-10 form has been created and shared in Titanium for you to use. You have

also been emailed with the CORE-10 form attachment. Please follow these steps: 1) Find

the email with subject "OM10 UK Sample Version 2.xml"; 2) Save the attached file to

your desktop; 3) In Titanium: *Configure - System Configuration – [Notes and Data Forms]*

– {Data Forms}; 4) Click {Import}; 5) Go to your desktop, click on the file saved from the

email and right click {Open}; 5) In Titanium: the data form will be at the bottom of your

list of forms.

Please note: The file will keep the name of the form and add on "Imported

mm/dd/yyyy" to the form name

How do I order the forms?

There are a number of ways you may wish to order the forms. You may choose to order

the presentation of the forms to the client by adjusting your setting in Titanium© in the

"web component" feature: 1) *Configure – Web component – Web component menu –*

New* ; 2) *or you may edit an existing label by selecting – *menu option label*

The order of the presentation of the forms to the client is determined by the order in

which they are ranked in this setting; this is the rank order of items selected in the

design of each form. For some centres that use their receptionist to upload the relevant

forms, you may choose to add a reminder on the client's appointment to ensure the

correct forms are administered in the correct order. If you choose to do so please also

inform all staff, including admin staff, of the anticipated changes. If you would like

advice on ordering the forms in a way which suits your service, please contact the

research team.

How do I export the data?

You may choose to export the data from Titanium© by following these steps: 1)Go to

Reports; 2) In the open dialogue box select – *data form statistics;* 3) Select the relevant

date range you would like to export; 4) Select – *export details* – to Microsoft Excel.

This will export ALL forms completed by ALL clients during the selected date range. The

clients that were not involved in the service development may be deleted from the Excel

spreadsheet by deleting the row of each excluded client. For the remaining, relevant

clients, simply replace their Titanium Client Number, with a Study ID provided in the

"**UK_norms_site1**" document. Exporting the data in this way will produce separate

sheets for CCAPS-62, CCAPS-34 and CORE-10. You may choose to either leave the sheets

separate with the study ID at the start of each sheet, or you can paste the data from all

sheets into one sheet with the study IDs in the first column.

If you would prefer to input the data manually, please see the following section.

How do I anonymise the data?

You have been emailed with two Microsoft Excel documents with the filename example

format "**uk_norms_site1**" and "**key1 (do not share)**" where "site1" is a unique number

which refers to your counselling centre. The document titled "key" contains a list of

study ID's with an empty adjacent column. Please use this spreadsheet to log your client

names with the corresponding study ID and do not share this with anyone. The key is for

you to track which clients correspond to the study IDs in case additional information in

needed in the future. The document titled "**uk_norms_site1**" contains an empty

spreadsheet with headers that correspond to the data to be inputted for the purpose of

the CORE-10/CCAPS comparison. In your own time, please complete the spreadsheet by

inputting the relevant data in the relevant cells. We appreciate that this is a time

consuming task and we are grateful for your contribution in this unique opportunity. If

you would like help inputting the data or propose a more time efficient method, please

contact the research team.

Important: Please ensure that no personal identifiable data is entered in the Excel

document. Please do not share the key with anyone outside of your counselling service

How do I share the anonymised data?

Once the spreadsheet titled "**uk_norms_site1**" is complete, please email it to:

elbroglia1@sheffield.ac.uk with the subject of the email titled "UK norms site1 data"

What happens next?

If you are ready to import the forms into Titanium©, please follow the instructions

provided in this guide. If you have questions or would like assistance preparing for the

proposed data collection period, please contact the research team as detailed below.

How do I inform my staff?

Guidelines may be shared with all counselling staff intending to support this proposed

service development. You have also been provided with reminder posters for your

counselling staff to put up in their rooms. Participating sites are encouraged to discuss

these proposed changes with all staff members before the proposed start date of

development.

Who can I contact for assistance?

If you or your counselling staff has any questions, please contact:

Appendix D2

Ethical approval letter for the pilot study that explored the acceptability, feasibility, and initial psychometric properties of the CCAPS clinical measure (email)

From: **Psychology Research Ethics Application Management**

System <no_reply@psychologyresearchethicsapplicationmanagementsystem>

Date: 22 April 2015 at 10:44 ref:1144

Subject: Approval of your research proposal

To: A.Millings@sheffield.ac.uk

Your submission to the Department of Psychology Ethics Sub-Committee (DESC) entitled

"An opportunistic service development comparison of CORE-10 and CCAPS outcome

measures in UK university counselling services. " has now been reviewed. The

committee believed that your methods and procedures conformed to University and

BPS Guidelines.

I am therefore pleased to inform you that the ethics of your research are approved. You

may now commence the empirical work.

Yours sincerely,

Prof Paul Norman

Acting Chair, DESC

Appendix D3

Scree plot of Eigenvalues from the Exploratory Factor Analysis (EFA) performed on the CCAPS data from the validation study

Scree plot from EFA on CCAPS-62 items
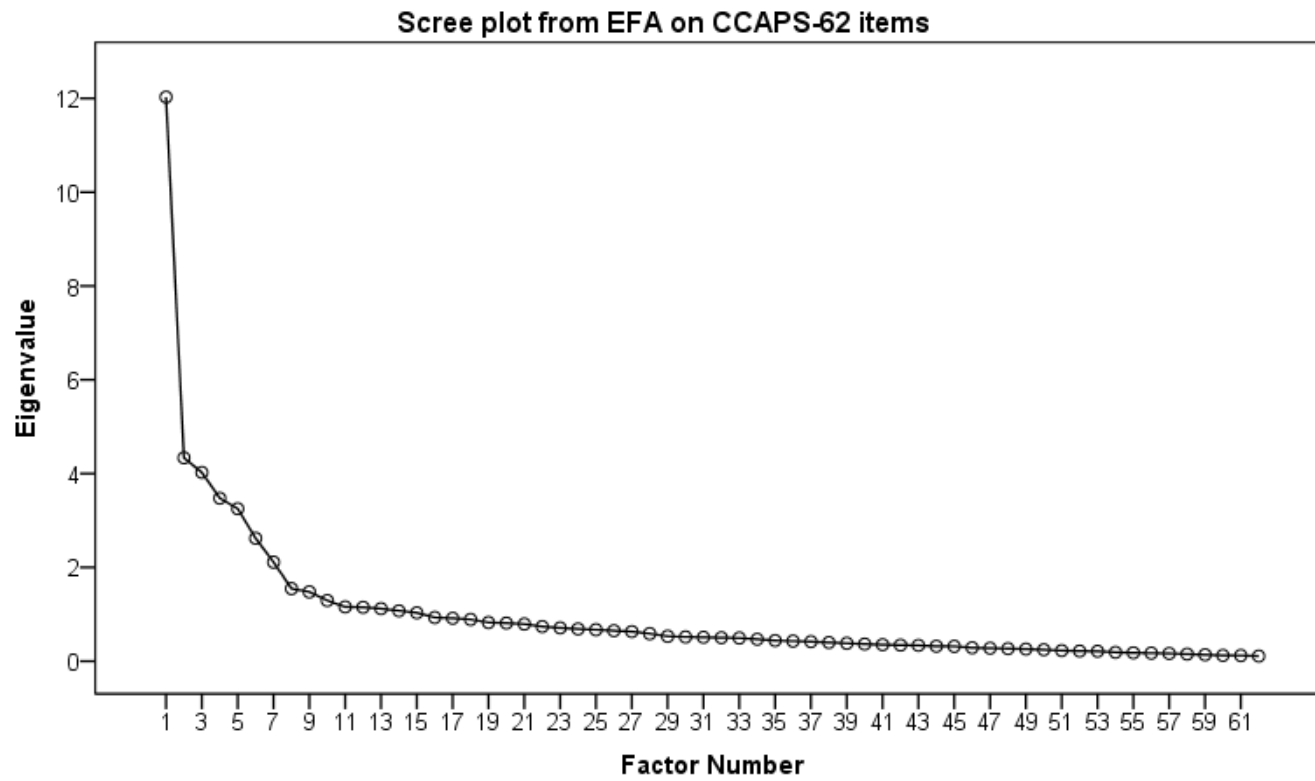
Appendix E1

Application form and materials submitted to the research ethics committee for an online survey version of the CCAPS measure with non-help-seeking students (email)

On 16/12/2015 13:34, Emma L Broglia wrote:

Hi Tom,

I'm writing ethics on a project for distributing an online clinical tool to 'nonclinical'

Students across various Universities in the UK. My supervisors and I are part of a special

interest group for establishing UK norms in student mental health. A previous project in

my PhD collected data from a student clinical sample and members in the group are

now agreeing to collect data from nonclinical students from any university in the special

interest group that would like to take part. I wonder if you could advise on two main

queries:

1) If we state in the ethics application that the online survey link will be circulated to a

primary contact at each participating university who will then distribute the survey to

their students, would the ethics from Sheffield cover data collection at participating

universities or would each university have to submit their own ethics application?

2) This study follows on from a previous study in my PhD as we essentially wish to

repeat the study across more universities which a few tweaks, having learnt from the

first study. With this in mind, do we start a new separate ethics application?

If it helps, the previous study has finished and we have analysed the data. Any advice

would be greatly appreciated.

Appendix E1 (cont'd)

Application form and materials submitted to the research ethics committee for an online survey version of the CCAPS measure with non-help-seeking students

An outline of changes proposed for research the Research Ethics Committee

This document provides an overview of changes proposed as an extension to an existing

research project with ethical approval from the Department of Psychology Ethics

Committee.

Postgraduate Name:	Emma L Broglia
Research Staff:	Professor M Barkham; Dr A Millings

Original research aims

1. Collaborate with university counselling services using or intending to use CCAPS

2. Facilitate planned service development in university counselling services

   intending to administer CCAPS alongside CORE-10

3. Analyse anonymised data on CORE-10 and CCAPS measures from collaborating

   counselling services to explore the construct of the two outcome measures

4. Validate CCAPS in a UK student sample

New research aims

1. Collaborate with a wider pool of university counselling services using or

   intending to use CCAPS; including new services which have since joined the

   collaborative initiative

2. Facilitate planned service development in new university counselling services intending to implement CCAPS

3. Repeat anonymised data collection in the original university counselling services intending to administer CCAPS alongside CORE-10 at a different academic time point

4. Analyse anonymised data on CCAPS and CORE-10 to explore sensitivity to change and confirmatory factor analysis on the outcome of original analysis

5. Capture CCAPS data on a non-clinical sample of students enrolled at participating universities to develop a control comparison sample to establish UK norms on student mental health

Justification for proposed changes

Since starting the original planned research, more university counselling services have decided to implement CCAPS into routine practice and have expressed an interest in collaborating with existing universities. This has been viewed to be advantageous for collecting data from a more geographically diverse student population whilst also supporting services that have taken the initiative to be more research active. Furthermore, analysis on original data suggested subtle differences across sites with respect to the psychological symptoms students presented with. This may give rise to potential symptom clusters which are specific to location or institution and warrants further investigation.

Compared to the CCAPS US Normative Sample, UK university students in the original research project obtained higher symptom severity on every CCAPS measure. However, as data collection was predominantly from two sites, analysis on a larger geographically

diverse sample is required to consolidate this finding. Furthermore, if symptoms remain elevated in phase 2 of data collection then comparison to a control group would be necessary to determine the extent to which symptoms are elevated within a UK population. Therefore the new research project proposes to administer an online version of CCAPS to non-clinical students enrolled at participating universities.

Lastly, services in the original research project observed potential differences between how CCAPS and CORE-10 are sensitive to change. Using a clinical measure which is sensitive to change is particularly important in University counselling services because treatment is confined to a short period of time to fit within the academic term times. Therefore is it important for a clinical measure to be sensitive to change to be more responsive to the service context. This analysis was not feasible in the initial research because the scheduling software which runs CCAPS does not clearly indicate whether a client has completed therapy nor the reason for ending therapy (e.g. planned ending or drop-out). Because of this it was not possible to compare pre-post CCAPS scores in order to calculate clinical reliable change. Analysing clinical reliable change in CCAPS and benchmarking it to CORE-10 as a UK standard, is the final stage required to validate use of CCAPS in a UK population.

To limit the burden on new university counselling services implementing CCAPS, the new research project proposes to only administer CCAPS with CORE-10 in the original group of participating universities. This will require little to no training as staff are already trained and experienced in administering CCAPS with CORE-10 and materials have already been implemented. The only proposed amendment would require adding a new data entry field to the existing electronic form to indicate: i) last counselling session and; ii) reason for last session.

Methods: Distributing CCAPS online to non-clinical students

With permission from the Centre for Collegiate Mental Health CCMH
(http://ccmh.psu.edu/) who support use of CCAPS, an online version of CCAPS will be
created in Qualtrics (http://www.qualtrics.com/) under the departmental licence. The
survey link will be shared with primary contacts at each collaborating university to
distribute the link to students enrolled at each university. Personal data will not be
collected to allow responses to remain anonymous. Instead, a series of demographic
questions will be asked to help characterise sub-populations. The form below displays
the demographic questions.

Institution Name	
DOB (dd/mm/yyyy)	
Course subject	
Gender	Male
	Female
	Transgender
	Rather not say
Year of study	
Mode of study	Full time
	Part time
Nationality	
Student type	Home/EU
	International
Reasons (1st, 2nd):	

Appendix E2

Ethical approval letter for the online survey version of the CCAPS measure with non-help-seeking students (email)

From: Thomas Webb <t.webb@sheffield.ac.uk> 17 December 2015 at 11:43

To: Emma L Broglia <elbroglia1@sheffield.ac.uk>

Hi Emma,

For information this was application #1119. Your proposed changes seem like a logical

extension of your original work and do not seem to have additional ethical ramifications.

I am therefore happy for you to conduct this additional work under the approval that

you received for the original project. Good luck with the research!

With best wishes,

Tom

As Chair DESC

Appendix E3

Table of p values from Bonferroni corrected post-hoc simple effect analyses conducted following a 5 x 8 mixed factorial ANOVA comparing CCAPS symptom cluster by faculty

		Arts	Engineering	Medicine	Science	Social Science
	N	753	143	313	927	678
Arts (n = 753)						
Depression		-	.258	.323	.452	.096
Generalised anxiety		-	.001*	.259	.463	.063
Social anxiety		-	.254	.001*	.152	.023
Academic distress		-	.358	.145	.096	.059
Eating concerns		-	.965	.369	.296	.354
Hostility		-	.245	.953	.114	.146
Alcohol use		-	.201	.246	.312	.136
Distress index		-	.326	.955	.063	.345
Engineering (n = 143)	Arts	Engineering	Medicine	Science	Social Science	
Depression	-	-	.065	.354	.260	
Generalised anxiety	-	-	.016	.265	.001*	
Social anxiety	-	-	.263	.196	.612	
Academic distress	-	-	.124	.096	.369	
Eating concerns	-	-	.359	.035	.320	
Hostility	-	-	.059	.200	.088	
Alcohol use	-	-	.036	.390	.132	
Distress index	-	-	.268	.401	.185	

Appendix E3

Appendix E3 (cont'd)

Table of p values from Bonferroni corrected post-hoc simple effect analyses conducted following a 5 x 8 mixed factorial ANOVA comparing CCAPS symptom cluster by faculty

	Arts	Engineering	Medicine	Science	Social Science
N	753	143	313	927	678
Medicine (n = 313)	Arts	Engineering	Medicine	Science	Social Science
Depression	-	-	-	.362	.258
Generalised anxiety	-	-	-	.074	.134
Social anxiety	-	-	-	.324	.001*
Academic distress	-	-	-	.851	.620
Eating concerns	-	-	-	.032	.913
Hostility	-	-	-	.085	.460
Alcohol use	-	-	-	.923	.621
Distress index	-	-	-	.241	.362
Science (n = 927)	Arts	Engineering	Medicine	Science	Social Science
Depression	-	-	-	-	.345
Generalised anxiety	-	-	-	-	.258
Social anxiety	-	-	-	-	.126
Academic distress	-	-	-	-	.358
Eating concerns	-	-	-	-	.125
Hostility	-	-	-	-	.963
Alcohol use	-	-	-	-	.854
Distress index	-	-	-	-	.623

*Bonferroni corrected p value = 0.002 (0.05/30)

Appendix E4

Table of p values from Bonferroni corrected post-hoc simple effect analyses conducted following a 3 x 8 mixed factorial ANOVA comparing CCAPS symptom cluster by help-seeker status

	Previous help (n = 640)	Current help (n = 236)
Avoided help (n = 488)	p value	p value
Depression	.252	.004
Generalised anxiety	.198	.006
Social anxiety	.077	.004
Academic distress	.892	.010
Eating concerns	.995	.917
Hostility	.953	.408
Alcohol use	.659	.198
Distress index	.207	.005
Current help (n = 236)		
Depression	.039	-
Generalised anxiety	.015	-
Social anxiety	.088	-
Academic distress	.006	-
Eating concerns	.909	-
Hostility	.332	-
Alcohol use	.863	-
Distress index	.015	-

*Bonferroni corrected p value = 0.002 (0.05/24)

Appendix E5

Mean and SDs for CCAPS subscale scores from the total sample of students that completed the CCAPS survey compared with the sample after removing 10% of self-reported help-seekers

	Means (Rank)		SDs	
	Group 1	Group 2	Group 1	Group 2
	(n = 2108)	(n = 1870)	(n = 2108)	(n = 1870)
Depression	2.02 (4)	2.00 (4)	0.75	0.75
GAD	1.93 (5)	1.94 (5)	0.82	0.81
Social Anxiety	2.08 (2)	2.05 (2)	0.88	0.88
Academic Distress	2.53 (1)	2.52 (1)	0.93	0.92
Eating Concerns	1.17 (8)	1.12 (8)	0.95	0.92
Family Distress	1.31 (6)	1.32 (6)	0.97	0.95
Hostility	1.18 (7)	1.17 (7)	0.83	0.81
Substance Abuse	1.08 (9)	1.05 (9)	1.02	1.01
Distress Index	2.06 (3)	2.05 (3)	0.68	0.68

Group 1 = Total sample

Group 2 = Total sample with self-selected help-seekers removed (n = 238)

Appendix F1

Application form and materials submitted to the research ethics committee for a feasibility trial comparing counselling alone with counselling supplemented with a well-being app for students experiencing anxiety or depression

Ethics Application #006171

Applicant details

Created: Wed 12 August 2015 at 06:45

First name: Emma

Last name: Broglia

Email: elbroglia1@sheffield.ac.uk

Programme name: PhD Psychology (ft)

Module name: PhD study 4, Feasibility Trial

Last updated: 14/12/2015

Department: Psychology

Date application started: Wed 12 August 2015 at 06:45

Applying as: Postgraduate research

Research project title: A feasibility trial comparing embedded university counselling versus counselling supplemented with a wellbeing app for students with anxiety or depression

Basic information

1. Supervisor(s) Michael Barkham m.barkham@sheffield.ac.uk

2: Proposed project duration Proposed start date: Mon 4 January 2016; Proposed end date: Mon 1 August 2016

3: URMS number (where applicable)

URMS number

- not entered -

4: Suitability

Takes place outside UK? No

Involves NHS? No

Healthcare research? No

ESRC funded? No

Involves adults who lack the capacity to consent? No

Led by another UK institution? No

Involves human tissue? No

Clinical trial? Yes

Social care research? No

5: Vulnerabilities

Involves potentially vulnerable participants? No

Involves potentially highly sensitive topics? Yes

Summary of research

1. Aims & Objectives

The primary aim is to demonstrate whether a well-being mobile phone app can be

integrated with face-to-face counselling in an embedded university counselling service.

For this purpose, the secondary aims are as follows: 1) Identify client characteristics

appropriate for supplementing counselling with well-being app; 2) Explore the

usefulness of app features for facilitating client-counsellor discussion; 3) Explore

differences in therapeutic alliance between clients receiving counselling versus

counselling supplemented with well-being app; 4) Explore service contribution to client's university experience, service satisfaction and academic coping; 5) Explore treatment preference and acceptability of randomisation; 6) Refine recruitment method and estimate expected recruitment period for RCT; 7) Estimate sample size for an adequately powered RCT; 8) Estimate completion rate at 3-month and 6-month follow-up; 9) Finalise resource needs to inform funding application for full RCT; 10) Inform cost-effectiveness of full intervention.

2. Methodology

Setting:

The trial will take place at the University of Sheffield student counselling service which receives approximately 1,300 student referrals annually . Strong relations have been formed with the University Counselling Service (UCS) through previous research activities and staff are committed to supporting the trial.

Timeframe:

Staff training and implementation will commence in January 2016 and will be reviewed before recruitment commences. Following the review, data collection will commence and will last 12-weeks during term time. Recruitment will occur in the first 2-3 and the remaining time will be dedicated to offering up to 6 counselling sessions for participants in both treatment conditions. Follow-up measures will also be sought 3-months and 6-months after entry into the trial.

Therapists:

Therapists who are accredited by the British Association of Counselling and

Psychotherapy (BACP) or the UK Council for Psychotherapy (UKCP), and are employed

by the University counselling service, will be eligible for the trial. A total of 6 therapists

have been assigned to support the trial, both in development and delivery, and will

receive specific training. Therapists will be asked to complete a brief intake

questionnaire to capture their model of practice and specific therapeutic style.

Therapists will also be provided with the BACP competency framework and the service's

most recent clinical handbook to ensure best practice.

Support will be available to therapists throughout the trial with the option of a weekly

drop-in session with a researcher on site and with fortnightly group meetings with the

head of service. All therapists will deliver counselling to clients in the control condition

(treatment as usual) and in the intervention condition (counselling supplemented with a

behavioural tracking mobile phone app) to control for therapist effects. However,

contamination across conditions is not anticipated because delivery of the intervention

relies specifically on the counsellor utilizing the app during sessions to aid discussion and

review goals; this will not be available to clients in the control condition.

Training and implementation:

The trial will be initially presented in a UCS staff meeting with the head of service and a

member. The trial will be initially presented in a UCS staff meeting with the head of

service and a member of the research team. The aim of the initial meeting is to provide

an opportunity for counsellors to ask questions and decide whether they would like to

support the trial. During the meeting, counsellors will have the opportunity to use the

mobile phone app whilst being led by the researcher to explain various app

functionalities. Staff will be presented with examples of how the app may be utilised

between and within face-to-face counselling sessions. After the meeting, counsellors

will be encouraged to use the app in their own time over the following week.

Counsellors will later receive a brief online evaluation form to critique the app and its

appropriateness for integrating with face-to-face. All counsellors will receive training to

address the following: recruiting clients, using audio recording devices, how to proceed

when a client withdraws from the trial, and how to report risk.

Various scenarios will be practised leading up to the trial to ensure that

counsellors are confident with technical and administrative requirements of the trial.

This may include using tablets/tablets to log-on to a dummy app user account

containing fake data to encourage counsellors openly navigate around various app

features. Role-play style sessions will be used to practice recruitment during triage

sessions and various scenarios which may arise in the intervention condition.

Counsellors will be asked to share their observations with the group and a session

summary will be added to training packs. As part of the implementation phase,

electronic versions of the trial outcome measures (described below) will be added to the

electronic scheduling system. Outcome measures will be introduced to staff at the initial

staff meeting and will be addressed in training where appropriate.

Participants:

The trial aims to recruit 40 students approved for university counselling and meeting

clinical cut-off for anxiety (10 on PHQ-9) or depression (10 on GAD-7). Clients will be

allocated to a condition based on the counsellor's clinical judgement at triage. This will

involve deciding on the client's appropriateness for receiving counselling supplemented

with a behavioural tracking well-being app. Treatment preference will be discussed and

clients will be informed on their allocation before consent is sought.

Inclusion criteria:

Participants will be invited into the trial if they meet the following criteria:

1. Registered student at the University of Sheffield

2. Approved for counselling (based on clinical judgement at triage)

3. Meet clinical cut-off for anxiety (10 on PHQ-9) or depression (10 on GAD-7)

Exclusion criteria:

Participants will be excluded if they meet the following criteria:

1. Present high risk to self or others

2. Currently receive therapeutic support

3. Currently taking prescribed psychotropic medications; or due to start during the trial

4. Have complex mental health problems

Recruitment:

Clients approved for counselling at their triage session will be provided with a study

booklet by their therapist and a brief summary of the trial will be explained. As

therapists book the first counselling appointment, clients will be asked if they would like

to book a study information session with a researcher prior to their counselling

appointment. Any client who books a study information session will be flagged on the

scheduling software to inform the researcher and to prompt a text message reminder

for the client 24 hours before the appointment. Clients will have the opportunity to

discuss the study in more detail with a researcher on site directly after their triage

should they choose to otherwise they will have the opportunity in their study slot. After

triage, therapists will complete an electronic outcome form detailing the client's

appropriateness for receiving counselling supplemented with the behavioural tracking

well-being app. It is standard practice to ask clients to arrive 10 minutes early to their

counselling appointment to complete clinical forms. For the purpose of the trial, the

study session with clients has been scheduled to last approximately 20 minutes, but will

include the clinical forms required for standard practice and will therefore only require

an additional 10 minutes of client time.

The aim of the study session is to inform clients of the goals of the trial and to

provide an opportunity to ask questions. Clients will be informed that they may have the

opportunity to receive counselling supplemented with a behavioural tracking well-being

app in the trial, if they meet eligibility. Written informed consent will be obtained and

clients will be asked to complete paper versions of PHQ-9 and GAD-7. Whilst the

researcher scores their responses, clients will be asked to complete CCAPS-62 and

CORE-10 on an tablet, in line with standard practice. Clients who meet clinical

cut-off for anxiety (10 on PHQ-9) or depression (10 on GAD-7) will be asked for their

treatment preference and informed of their therapist's judgement on which condition

they would be most appropriate for.

The outcome of the session (eligibility and client's participation decision) will be

completed on an electronic form which will notify the therapist before the counselling

session is due to start. Participating clients in the intervention condition will be provided

with an app booklet with instructions on how to install the app on their mobile phone

and to use specific features. This booklet will also be available to therapists to aid

discussion in the counselling session (attached). Participating clients in the control

condition will be provided with a version of the participant information booklet which

does not contain information on the app (attached). This booklet will contain

information on the aims of the trial and the importance of capturing data from a control

comparison group. All versions of the booklet will detail reasons for administering the

study measures at each time point and will provide expected dates for the 3-month and

6-month follow-up measures. Here participants will also be informed that a £10

shopping voucher will be posted to participants at 3-months and again at 6-months to

acknowledge their time spent completing the additional research measures. Vouchers

will be posted by the UCS and envelopes will not contain any information to indicate

that they have been sent from the UCS.

Postage costs will be covered by the research team. Non-participating clients

will be thanked for their time and directed back into the waiting room for their therapist

to collect them for their first counselling session. Participants will be entitled to keep the

study information booklet should they choose to. The back of the booklet will provide

contact details of the counselling centre, emergency/crisis numbers, and a university

contact for complaints on the occasion that clients would like to make a complaint

about the research. Following completion of the study information session, clients will

be directed to their first counselling session. A detailed trial process document has been

attached and the participant flow diagram is displayed in figure 1.

Intervention:

All participants will receive an active treatment in line with standard practice and

therefore will not be disadvantaged by participating in the trial. Participants have access

to the standard level of care at Sheffield UCS; which includes a waiting period

dependent on service availability, but is typically shorter than NHS services. In 2013/14,

the typical waiting periods for Sheffield UCS were 3-5 working days for initial session

(service agreement states within 10 days) and 8-10 working days for ongoing sessions.

Once participants enter the trial, they will be allocated to one of two conditions: 1)

counselling in line with the service's standard practice (control); 2) counselling

supplemented with a behavioural tracking well-being app (intervention). Participant's

treatment preference (control or intervention condition) will be recorded, however,

their allocation will be determined by Therapist's clinical judgement on their

appropriateness for receiving counselling supplemented with a behavioural well-being

app. On the occasion where clients would prefer to join a condition which does not

agree with their therapists clinical judgement the therapist will be asked to join the

study information session to address the client's concerns. This discussion will

determine the client's allocation to a condition, however this discrepancy is not

anticipated because anecdotal evidence suggests that clients and therapist are in

agreement in the outcome of the triage appointment. A breakdown of components

across each condition is presented in table 2 (page 8) of the attached protocol. The

participant flow diagram is presented in page 9 of the attached protocol.

Counselling as standard treatment (control):

Up to 6 sessions of face-to-face counselling will be offered to participants in line with

standard practice at Sheffield UCS. Sessions will be 50-minutes in length and the

frequency of sessions will be determined through counsellor-client discussions. If

participants are shown to require more than 6 sessions, treatment will continue outside

of the trial and will be supported by the counselling centre. On this occasion, trial data

will only be collected up to session 6. Therapists will be asked to briefly describe their

model of practice and specific therapeutic style to enrich understanding of the service's

standard of practice.

Counselling supplemented with well-being app (intervention):

Up to 6 sessions of face-to-face counselling will be offered to participants in line with

standard practice at Sheffield UCS. Sessions will be 50-minutes in length and the

frequency of sessions will be determined through counsellor-client discussions. As well

as the standard level of care, counselling sessions will be supplemented with guided use

of a behavioural tracking well-being app to promote engagement between face-to-face

sessions. The well-being app will be used on an tablet during counselling sessions to

facilitate discussion and to aid the decision process for setting goals and reviewing client

progress. Through these discussions, clients will be guided through various app features

to decide on which activities would be beneficial to use between face-to-face sessions.

App features may include: 1) Behaviour tracking: mood, thoughts, sleep, relationships,

time outside, alcohol and more; 2) Reflective thinking: guided CBT, mindfulness and

positive visualisation exercises; 3) Guided relaxation: breathing, meditation and body

scanning exercises; 4) Peer led support: through participation with anonymous online

communities.

Clients will be randomly prompted to engage with the app daily and to log

various behaviours. Clients will also be encouraged to prepare for their counselling

sessions by reflecting on their diary entries and deciding on what they would like to

address in the session. During face-to-face sessions, therapists will be encouraged to

review client's app activity, discuss the client's reflections and progressively adjust goals

where appropriate. Therapists will be provided with an tablet to use with clients in

sessions which may include clients accessing their app account to display their activities

with their therapist. Sessions will also be audio-recorded with the tablet to be more

discrete than traditional recording equipment. Audio recordings will be analysed to

explore how various app features are discussed during counselling sessions. For this

reason, audio recording will be specific to the intervention condition and clients in the

control condition will not be audio recorded.

Measures: Clinical Outcomes

CORE-10: The 10-item Clinical Outcomes in Routine Evaluation Outcome Measure

(http://www.coreims.co.uk) will be administered at triage (intake), every counselling

session and at 3-month and 6-month follow-up to measure symptom severity.

Statements refer to the previous week and are scored on a 5-point Likert scale (0=not at all; 4=most or all of the time), whereby higher scores indicate higher symptom severity. Items also provide measures on the following subdomains: subjective well-being; anxiety; depression; physical problems; trauma; general functioning; functioning of close relationships; functioning of social relationships; risk to self; risk to others. CORE-10 has been viewed as a proxy for CORE-OM which has been used widely in psychological services across the UK and is standard practice in many university counselling services.

CCAPS-34: The 34-item Counselling Centre Assessment for Psychological Symptoms (Locke et al, 2011) will be administered at triage (intake), every counselling session and at 3-month and 6-month follow-up to measure psychological symptoms specific to university students. Items refer to the previous 2-week period and are scored on a 5-point Likert scale (0=not at all like me; 4=extremely like me), whereby higher scores indicate higher symptom severity. Items also provide scores on the following subdomains: depression; generalised anxiety; social anxiety; academic distress; eating concerns; hostility; alcohol use; and suicide ideation. CCAPS is the only measure designed to detect psychological symptoms in university students specifically and has been used widely in student counselling centres in USA. The measure was recently introduced in the UK and has been used alongside CORE-10 at Sheffield UCS in a previous validation study (ethical approval by the Department of Psychology Sub-Committee DESC on 22/04/2015).

PHQ-9: The 9-item Patient Health Questionnaire will be administered in the consent session to determine eligibility. Clients who reach clinical cut-off for depression (scores 10+) or anxiety (scores 10+) on GAD-7 will be invited into the trial. Items refer to the last

two weeks and are scored on a 4 point Likert scale (0=not at all; 3=nearly every day).

Higher scores indicate higher severity, with scores over 11 reaching clinical cut-off.

GAD-7: The 7-item General Anxiety Disorder measure will also be administered in the

consent session to determine eligibility. Clients who reach clinical cut-off for anxiety

(scores 10+) or depression (scores 11+) on PHQ-9 will be invited into the trial. Items

refer to the last two weeks and are scored on a 4 point Likert scale (0=not at all;

3=nearly every day). Higher scores indicate higher severity, with scores over 11 reaching

clinical cut-off.

Measures: Academic coping:

Clients will be asked questions about their opinion on their ability to cope academically,

at pre and post counselling. The theme of academic coping will also discussed in follow-

up telephone interviews. Participants will be asked various questions to indicate

whether their mental health is impacting their studies (or vice versa) and whether they

believe that counselling has helped with their university retention and overall

experience.

Measures: Resilience

The 10-item Connor-Davidson Resilience Scale (Campbell-Sills & Stein, 2007) will be

administered at intake to measure resilience and psychological functioning. Items refer

to the previous month and are scored on a 5-point Likert scale (0=not true at all; 4=true

nearly all of the time), whereby higher scores demonstrate better resilience. As

indicators of resilience, CD-RISC 10 measures an individual's ability to tolerate change,

pressure, personal problems, negative outcomes, painful feelings and illness - all

common experiences for university students. The CD-RISC 10 is a short version of the

original CD-RISC 25 (Connor & Davidson, 2003) which has good internal consistency, good construct validity, and has been demonstrated to have a factor structure which is more stable than CD-RISC 25 (Campbell-Sills & Stein, 2007).

Measures: Therapeutic Alliance

The 12 item Working Alliance Inventory-Short Form (Hatcher, R. L & Gillaspy, J. A, 2006) will be administered at session 3 to measure the strength of therapeutic alliance. Items refer to client's current views on their therapist and are rated on a 5-point Likert scale (1=strongly disagree; 5=strongly agree) whereby higher scores indicate stronger therapeutic alliance. Items also provide scores on three distinct components of therapeutic alliance including: 1) agreement of therapy tasks; 2) agreement of therapeutic goals and; 3) presence of an affective bond between clients and therapists. These components are particularly important for the exploring the impact of supplementing face-to-face counselling with a behavioural tracking well-being app.

Measures: Service impact

CSQ-8: The 8-item Client Satisfaction Questionnaire will be administered after the last counselling session as a global measure of client satisfaction (Attkinsson & Zwick, 1982). Items refer to client's overall service experience and are rated on a 4-point Likert scale (1=quite dissatisfied; 5=very satisfied) whereby higher scores indicate greater satisfaction. Many counselling services report on client satisfaction to allow comparison to other services and to ensure that services respond to client feedback. Capturing client satisfaction will also allow comparisons between clients allocated to the control condition (treatment as usual) and the intervention.

Contribution to institution: It is particularly important for embedded counselling services to demonstrate impact on the wider institution to support funding and service development. Many embedded counselling services already employ their own feedback forms which typically concern the following: i) whether students believe that counselling improved their university experience (experience); ii) whether counselling helped them to stay at university (retention); whether counselling helped them to cope better with academic requirements (academic); whether counselling helped them develop skills relevant for future employment (employability); whether counselling helped them to better cope with their relationships (relationship); whether they felt safe and supported through their experience (support); and whether they feel more resilient having received counselling (resilience). Questions tapping these domains will be administered alongside the CSQ-8 after the last counselling session. A summary of measures and their time of administration has been provided on page 14 of the attached protocol.

Pacifica App data

Private groups: Clients will be asked to use the private group feature in the app to privately share their data with the researcher through weekly prompts. The private group feature provides a unique group code which allows Pacifica app users to link their accounts. Users can only join the group via invitation with the unique group code and all members in the group are visible to allow users to know who has access to the group. Separate private groups will be set-up between the researcher and each participant in the intervention condition (n = 20). Participants will be informed that the private groups are for data sharing/research purposes only and will not be accessed by anyone other the primary researcher.

All information provided to participants will include a disclaimer stating that private groups should not be used for therapeutic support and clients should instead contact the 24-hour emergency/crisis helpline should they need to reach a therapist outside of their counselling sessions. Private groups will not be set-up between clients and therapists to ensure that this feature cannot be used as an out-of-hours service and to reduce risk concerns. Any diary entries, goals, achievements and completed exercises from the previous week can be shared in the private group. Diary data provides additional information on the times at which clients use the app as well as how many times the app is used each day.

Audio recordings:

Data shared with the researcher will be compared to information discussed during counselling sessions to explore what aspects clients choose to discuss or withhold from therapists. These data sources will be compared across counselling sessions to further explore components of therapeutic alliance and to capture how reliability of sources varies over time. Audio recordings will be analysed to explore the following: 1. How clients/counsellors discuss app activities; 2. How often clients/counsellors refer to app activities; 3. How clients/counsellors initiate discussion with app activities; 4. How many times discussion of a specific activity is repeated/reinforced; 5. How app features are used to facilitate discussion and decision making 6. What therapeutic styles are suited to being supplemented with a behavioural tracking wellbeing app; 7. What client characteristics are appropriate for receiving counselling supplemented with a behavioural tracking well-being app; 8. What techniques are used to integrate app features with face-to-face support; 9. Potential therapeutic benefit of individual features; 10. Potential reasons for deciding when to stop supplementing counselling with a behavioural tracking well-being app (if applicable)

Qualitative data collection:

Client and clinician experiences will be explored to inform study design and allow future investigation of moderators in the full RCT. In particular, clients in the intervention condition will be invited to take part in anonymised telephone interviews whilst counsellors will be invited to take part in a focus group.

Telephone interviews with clients

Clients in the intervention condition will be invited to take part in a follow-up telephone interview after their last counselling session to capture their experience during the trial. Only clients allocated to the intervention condition will be contacted for telephone interviews to allow exploration of app-augmented therapy. The primary aim of the telephone interviews is to refine trial design and to aid exploration of potential moderators in the full RCT. A range of factors will be explored which will address: how clients describe their overall experience of counselling, their therapist and the trial; what issues clients had with counselling, their therapist and the trial; whether clients felt as though they had benefitted from counselling and/or participating in the trial; whether clients felt they were disadvantaged by participating in the trial; which aspects of the trial they would improve, and how; client acceptability of randomisation procedure.

Focus groups with counsellors

Counsellors will be invited to take part in focus groups after the trial to capture their experience during the trial. The primary aim of the focus group is to refine training and procedures for a future RCT. The secondary aims of focus groups include: 1. Exploring potential moderators of engagement and therapeutic alliance; 2. Identifying techniques used to aid client-counsellor discussion; 3. Identifying client characteristics appropriate for supplementing counselling with a behavioural tracking well-being app Discussion

topics will include: 1. What expectations counsellors had before entering the trial and how their expectations may have changed throughout the trial; 2. Whether counsellors adjusted their counselling style to suit the trial, and how; 3. Whether counsellors felt they had benefitted from taking part in the trial, and how; 4. Whether counsellors felt they had been disadvantaged by taking part in the trial, and how; 5. How counsellors would feel more supported if the trial was repeated; 6. Counsellors' overall opinion of trial outcome measures; 7. What aspects of the trial they would change.

Discussion topics specific to the intervention condition will include: 1. Whether counsellors felt comfortable supplementing counselling with a well-being app and whether they would continue to use it in counselling; 2. Whether specific features facilitated client-counsellor discussion during sessions; 3. Whether counsellors thought that clients were more engaged in the intervention condition; 4. Issues which arose from using the well-being app; 5. What app features counsellors found to be the most useful; 6. Whether counsellors felt comfortable and confident using the app with clients; 7. Whether reviewing the app aided clients to acknowledge their progression; 8. Whether tracking behaviours caused confusion or concern A trial process document has been provided on pages 17-22 of the attached protocol.

3. Personal Safety

Raises personal safety issues? No

Personal safety management - not entered -

About the participants

1. Potential Participants

(see participant section above)

2. Recruiting Potential Participants

Clients approved for counselling at their triage session (their first visit to the counselling centre when their appropriateness for counselling is assessed by a therapist) will be provided with a study booklet (attached) by their therapist and a brief summary of the trial will be explained. As therapists book the first counselling appointment, clients will be asked if they would like to book a study information session with a researcher prior to their counselling appointment. Any client who books a study information session will be flagged on the service's scheduling software to inform the researcher and to prompt a text message reminder for the client 24 hours before the appointment (standard practice). Clients will have the opportunity to discuss the study in more detail with a researcher on site directly after their triage should they choose to otherwise they will have the opportunity in their study information slot.

After triage, therapists will complete an electronic outcome form detailing the client's appropriateness for receiving counselling supplemented with the behavioural tracking well-being app. It is standard practice to ask clients to arrive 10 minutes early to their counselling appointment to complete clinical forms. For the purpose of the trial, the study session with clients has been scheduled to last approximately 20 minutes, but will include the clinical forms required for standard practice and will therefore only require an additional 10 minutes of client time. The aim of the study session is to inform clients of the goals of the trial and to provide an opportunity to ask questions. Clients will be informed that they may have the opportunity to receive counselling supplemented with a behavioural tracking well-being app in the trial, if they meet eligibility. Written informed consent will be obtained and clients will be asked to complete paper versions of PHQ-9 and GAD-7; to assess their eligibility. Whilst the researcher scores their responses, clients will be asked to complete CCAPS-62 and CORE-10 on an tablet, in line with standard practice.

Clients who meet clinical cut-off for anxiety (10 on PHQ-9) or

depression (10 on GAD-7) will be invited into the trial and asked for their

treatment preference. They will be informed of their therapist's judgement on

which condition they would be most appropriate for (based on the triage

outcome). The outcome of the session (eligibility and client's participation

decision) will be completed on an electronic form which will notify the therapist

before the counselling session is due to start. Participating clients in the

intervention condition will be provided with an app booklet (attached) with

instructions on how to install the app on their mobile phone and to use specific

features. This booklet will also be available to therapists to aid discussion in the

counselling session. Participating clients in the control condition will be

provided with a version of the participant information booklet which does not

contain information on the app (attached).

This booklet will contain information on the aims of the trial and the

importance of capturing data from a control comparison group. All versions of

the booklet will detail reasons for administering the study measures at each

time point and will provide expected dates for the 3-month and 6-month follow-

up measures. Here participants will also be informed that a £10 shopping

voucher will be posted to participants at 3-months and again at 6-months to

acknowledge their time spent completing the additional research measures.

Vouchers will be posted by the UCS and envelopes will not contain any

information to indicate that they have been sent from the UCS. Postage costs

will be covered by the research team. Non-participating clients will be thanked

for their time and directed back into the waiting room for their therapist to

collect them for their first counselling session. Participants will be entitled to

keep the study information booklet should they choose to. The back of each

booklet will provide contact details of the counselling centre, emergency/crisis

numbers, and a university contact for complaints on the occasion that clients

would like to make a complaint about the research. Following completion of the

study information session, clients will be directed to their first counselling

session.

2.1 Advertising methods

Will the study be advertised using the volunteer lists for staff or students

maintained by CiCS? No

3. Consent

Will informed consent be obtained from the participants? (i.e. the proposed

process) Yes

This information has been detailed within section 2 for recruiting

participants. Consent forms have also been attached. Written informed consent

will be obtained from therapeutic staff at the initial staff meeting. This meeting

will include the head of service, the primary researcher (PhD student) and a

select number of therapists that have previously indicated an interest to be

involved with the trial. Staff at the counselling centre have been involved with

previous research activities, training events and meetings supported by the

candidates named on this application. The staff informed consent sheet has

been attached.

4. Payment

Will financial/in kind payments be offered to participants? Yes

Participants will not be financially incentivised to take part. However, all

participants will be posted a £10 shopping voucher during the 3-month and 6-

month follow-up stages of the trial. The follow-up stages are specific to the

research project and will occur after participants have completed their

treatment. The shopping vouchers are to acknowledge the time spent

completing additional research measures and will be posted in good will

irrespective of whether participants complete the measures.

5. Potential Harm to Participants

What is the potential for physical and/or psychological harm/distress to the

participants?

The severity of participants' mental health needs will be assessed by clinical

staff before contact is made with the researcher. Participants presenting with

high risk to self or others will not be invited into the trial. Should participants,

counsellors or researchers experience psychological harm/distress during the

trial, there will be immediate access to professionally trained clinical staff at the

counselling centre. Emergency and/or crisis services are also available through

the counselling service, should participants require additional, immediate

support.

How will this be managed to ensure appropriate protection and well-being of the

participants?

All participants within the trial receive active therapeutic treatment which

complies with the British Association for Counselling and Psychotherapy (BACP)

ethical framework and will be delivered in line with the services current clinical

manual. Participants will not be disadvantaged by taking part in the trial and

there are no risks anticipated. All information provided to participants/clients

will contain contact details for the 24-hour emergency/crisis helpline. All stages

of the project will take place at the university counselling centre where there

will be immediate access to clinically trained professionals. The follow-up

measured will be administered online and the participant interviews will be

conducted via telephone to limit physical access.

About the data

1. Data Confidentiality Measures

All information collected will be confidential and will only be accessible by members of

the research team. Data will be stored securely on an encrypted external hard drive and

backed-up on the University CICS security approved network. All devices will password

protected and audio files will be encrypted. Transcriptions from recordings will be

anonymous individuals will not be personally identifiable. Any confidential paperwork

(consent forms, paper versions of scoredPHQ-9 and GAD-7) will be stored securely in a

locked filing cabinet in a dedicated private room on site of the counselling centre. Trial

data will be kept by the research team for 10 years to allow time to submit funding

applications, publication and last for the duration of the anticipated RCT.

2. Data Storage

Data will be stored securely on an encrypted external hard drive and backed-up on the

University CICS security approved network. All devices will password protected and will

be housed at the university counselling centre. Audio files will be encrypted and

synchronized to the security approved, internal network for the counselling centre. Only

approved members of staff will have access to the files and each audio file will further

be password protected. Encrypted audio files will also be emailed to the head of service

as part of the synchronization procedure. This process will allow the head of service to

remain updated with the progress of the trial and to back-up encrypted audio files.

 Audio recordings: Data shared with the researcher will be compared to

information discussed during counselling sessions to explore what aspects clients

choose to discuss or withhold from therapists. These data sources will be compared

across counselling sessions to further explore components of therapeutic alliance and to

capture how reliability of sources varies over time. Audio recordings will be analysed to

explore the following: 1. How clients/counsellors discuss app activities; 2. How often clients/counsellors refer to app activities; 3. How clients/counsellors initiate discussion with app activities; 4. How many times discussion of a specific activity is repeated; 5. How app features are used to facilitate discussion and decision making; 6. What therapeutic styles are suited to being supplemented with a behavioural tracking wellbeing app; 7. What client characteristics are appropriate for receiving counselling supplemented with a wellbeing app; 8. What techniques are used to integrate app features with face-to-face support; 9. Potential therapeutic benefit of individual features; 10. Potential reasons for deciding when to stop supplementing counselling with a well-being app (if applicable).

Data will be analysed for scientific purposes only and will be disseminated in the form of scientific papers, presentations and potential conference proceedings. Data will also be used in a funding application to support the anticipated RCT. Trial data will be kept by the research team for 10 years to allow time to submit funding applications, publication and last for the duration of the anticipated RCT. Transcriptions from recordings will be anonymous individuals will not be personally identifiable. Any confidential paperwork (consent forms, paper versions of scored PHQ-9 and GAD-7) will be stored securely in a locked filing cabinet in a dedicated private room on site of the counselling centre. Trial data will be kept by the research team for 10 years to allow time to submit funding applications, publication and last for the duration of the anticipated RCT.

Consent forms relevant to project? Yes

Declaration

Signed by: Emma Broglia

Date signed: Mon 14 December 2015 at 13:51

External documentation

Participant information booklet: Intervention (counselling plus app)

This information booklet is to be handed out by a researcher during the study

information session for participants who have consented to join the condition for

counselling which is supplemented with a well-being app (intervention). The aim of the

booklet is to outline the aims and expected timeframe of the counselling & app

condition.

Welcome and thank you for joining the trial! The University of Sheffield Counselling

Centre is working closely with researchers to improve the service and contribute to

research evidence on student counselling. Participants will be offered to up to 6

sessions of counselling across a 12-week period and in line with standard practice at

Sheffield University Counselling Service (UCS). Sessions will be approximately 50-

minutes in length and the frequency of sessions will be determined through discussion

with your therapist. In addition to the standard level of counselling, you will have the

opportunity to use a well-being app within and between counselling sessions. Your

therapist will discuss various app features and activities with you during your counselling

sessions which may include using a tablet to view your app activities.

Through discussion with your therapist, you will be guided through various

features and activities which you will be encouraged to use between sessions. You may

also be asked to reflect on your activities in preparation for your next counselling

session or you may choose to do this with your therapist. Usage of the app will be

catered to your individual needs and will be reviewed at each counselling session.

Therapists will also use the tablet to audio record counselling sessions, with your

permission. Recording with the tablet aims to be more discrete than traditional

recording equipment to reduce disruption and to make you feel more at ease.

Pacifica is a smartphone app which offers daily tools for stress, anxiety and low mood. The features are based on Cognitive Behavioural Therapy (CBT), meditation and mindfulness. As well as the guided exercises, individuals may benefit from using the app to log and reflect on various moods and behaviours. The following information has been adapted from the Think Pacifica team website. If you'd like to read their aims in more detail, please visit https://www.thinkpacifica.com/.

Cognitive Behavioural Therapy (CBT): "is a well-established, highly effective, and lasting treatment... It focuses on identifying, understanding, and changing thinking and behaviour patterns... Clients are involved in their own recovery, have a sense of control, and learn skills that are useful throughout life." – Anxiety and Depression Association of America (ADAA)

Mindfulness meditation: It's been said that anxiety is worrying about the future and depression is dwelling on the past. Well, mindfulness teaches us to stay in the present moment. How does this help? When you're mindful, you learn to put space between your thoughts/feelings and observe them without judgement. In other words, instead of immediately reacting to a thought, you can respond more sensibly. Remember just because you think something, does not make it true.

Pacifica: the mission: *"Our reality is created through an ongoing cycle of thoughts, feelings and behaviours. Pacifica attempts to break this cycle using tools that target each of its components. Day-by-day, you'll learn to manage your feelings at your own pace. We're not about quick-fixes or false promises. We are about real progress, a day at a time."* The following page outlines each feature you may decide to use with the guided support from your therapist.
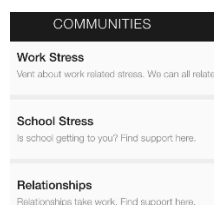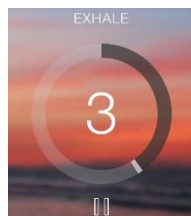
Mood tracking:

By consistently documenting our mood, we can start to identify both positive and negative life influences on our emotions. Research has shown that the process of simply checking in with current mood states can help us feel better about our lives.

Goal setting:

By identifying your mood, you will be able to establish goals for emotional change and choose specific goals tailored to alleviating a specific mood.

CBT Tools:

By logging and reflecting on your thoughts, you and your therapist will be able to detect behavioural patterns and adjust negative thinking.

Mindfulness meditation:

Through guided mindfulness meditations you will be able to learn how to stay in the present moment whilst putting space between your thoughts and judgements until you can respond at a more appropriate time.

Online communities:

There are various peer support groups available through the anonymous online community so you can reach out in the moment you need it the most.

Installing the app: The app is available on iOS and Android; simply use your phone to access your app store and search for "Pacifica". Once found, click on "Get" to view the app's terms and conditions and if you accept, proceed with the installation. Once installed, go into the app and create your unique user account. The app will display a tour of all the available features. This information can also be accessed any time by clicking on the question mark at the top of each screen. To unlock the full version of the app, you will be asked to type in your unique purchase code which has been provided on the first page of this booklet. If you require any additional support in installing the full version, you may contact the researcher (details on back page).

You have also been provided with a unique group code. In due course, you will receive a group invitation by the researcher. The group will only be accessible by the primary researcher and yourself, if you decide to join the group. The purpose of the group is to share data with the primary researcher to fulfil the aims of the trial. These groups will not be accessible to anyone other than the primary researcher.

Private groups will not be used as an out-of-hours service and therapists will not have access to private groups .

Should you need to reach a therapist outside of your counselling sessions you may contact the 24-hour UCS emergency/crisis helpline as provided on the back of this booklet. If you decide to join the group, you will receive weekly prompts to share your app data with the researcher, if you agree to do so.

What happens if the study stops earlier than expected?

On the unlikely occasion that the project does stop earlier than expected, you will continue to receive counselling by your therapist in line with the UCS.

Summary of stages

Attend up to 6 counselling sessions	→	If applicable, at session 3: online version of WAI-8	→	Last session: online exit questions with academic coping

3-months: online questions & £10 shopping voucher	→	6-months: online questions & £10 shopping voucher
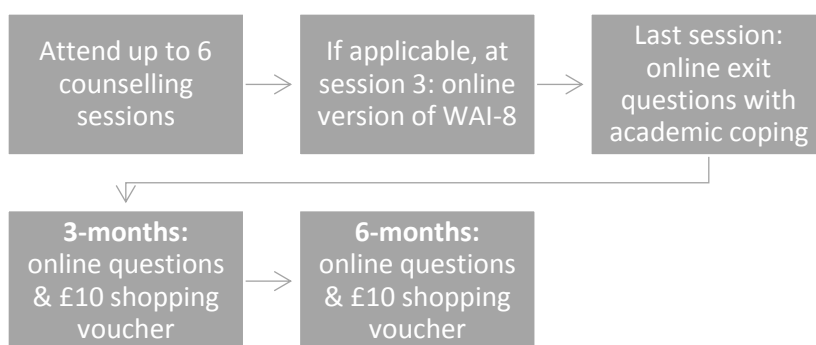
What if something goes wrong?

On the unlikely occasion that a problem arises during the project, it will be reported immediately and the research will end. If the project ends for this reason, you will continue to receive counselling by your therapist in line with the university counselling centre.

Will my participation be kept confidential?

Yes. All information collected will be confidential and will only be accessible by members of the research team. Data will be stored securely on an encrypted external hard drive and backed-up on the University CICS security approved network. Trial data will be kept by the research team for 10 years to allow time for the anticipated RCT.

What will happen to the results of the research?

Data will be analysed for scientific purposes only and will be disseminated in the form of scientific papers, presentations and potential conference proceedings. Data will also be used in a funding application to support the anticipated RCT. **Counsellors and clients will not be identifiable from any analyses or scientific reports**

What type of information will be measured and why?

You will be asked to arrive 10 minutes early for each counselling session to complete a series of questions on a tablet in the waiting room. These questions are part of routine

practice and help to guide your counselling sessions. You may have already completed these questions at the start of your triage appointment (see section on measures for more information).

Research measures: As part of the research process, you will be asked to complete additional questions at various time points throughout your counselling experience. These measures will be predominantly online and, you're your permission, you will receive email prompts with a web-link to complete the questions.

Service evaluation: After your last session of counselling you will be contacted by a researcher to complete a series of exit questions about your overall experience of the service. These questions may be answered over the phone or via an online form depending on your preference. During this time, you will also be asked various questions about your opinion on how counselling impacted your university experience and academic coping style.

3 and 6-month follow-up: At 3-months and 6-months from joining the study you will be asked to complete a series of questions similar to those you may have completed throughout your counselling experience. You will be contacted by a researcher at each time point as a reminder to complete the research measures. If you agree to complete the questions you may decide to answer them over the phone or via an online form depending on your preference.

Shopping vouchers: To acknowledge your time spent completing the additional research measures, you will be posted a £10 shopping voucher at 3-months and again at 6-months irrespective of whether you complete the measures. The vouchers will be posted to you by the counselling centre, but the envelopes will not indicate that they have been posted by the counselling centre to ensure that your involvement with counselling remains private.

A summary of measures has been provided below:

1. Clinical Outcomes in Routine Evaluation (CORE-10) will be used to measure psychological symptoms and is standard practice in many UK counselling centres (also follow-up measure).

2. Counselling Centre Assessment for Psychological Symptoms (CCAPS-34) will be used to measure students' psychological symptoms **(also follow-up measure).**

3. Patient Health Questionnaire (PHQ-9) will be used to measure depression; to screen for eligibility **(also follow-up measure).**

4. Generalised Anxiety Disorder (GAD-7) will be used to measure anxiety; to screen for eligibility. **(also follow-up measure).**

5. Clients will be asked questions about their opinion on their ability to cope academically, before and after counselling.

4. Connor-Davidson Resilience Scale (CD-RISC 10) will be used to measure psychological tolerance before counselling.

5. Working Alliance Inventory-Short Form (WAI-SF 12) will be used at session 3 to measure therapeutic alliance

6. Client Satisfaction Questionnaire (CSQ-8) will be used at the end of counselling as a global measure of client satisfaction

7. Service impact will be measured through various questions to clients about how they feel counselling has helped them to stay at university and fulfil their academic goals.

8. Pacifica data shared by clients will be used to explore usage between counselling sessions and to compliment audio recordings when exploring usage during counselling.

9. Audio recordings will be used to explore how various app features are discussed during counselling and to help identify potential moderators of therapeutic discussion.

10. Telephone interviews: participants who decide to take part in a follow-up telephone interview will be asked to describe their experience of counselling and of the project to inform design.

11. Focus groups: counsellors will be invited to discuss their experiences of counselling in a series of focus groups.

Who is organising and funding the research?

This project is funded by the British Association for Counselling and Psychotherapy (BACP) as part of a PhD scholarship at the University of Sheffield, undertaken by Emma Broglia. This project is being supervised by Professor Michael Barkham.

Who has ethically approved the research?

This research has received ethical approval from the University of Sheffield Research Ethics Committee in the Department of Psychology. This project also complies with the BACP ethical framework and with the Sheffield University Counselling Service, clinical handbook.

External documentation (cont'd)

Participant information booklet: control (counselling)

This information booklet is to be handed out by a researcher during the study information session for participants who have consented to join the counselling only (control) condition. The aim of the booklet is to outline the aims and expected timeframe of the counselling condition.

Introduction

Welcome and thank you for joining the trial! The University of Sheffield Counselling Centre is working closely with researchers to improve the service and contribute to research evidence on student counselling.

What will counselling involve?

Participants will be offered to up to 6 sessions of counselling across a 12-week period and in line with standard practice at Sheffield University Counselling Service (UCS). Sessions will be approximately 50-minutes in length and the frequency of sessions will be determined through discussion with your therapist. You will be asked to arrive 10 minutes early for each counselling session to complete a series of questions on a tablet in the waiting room. These questions are part of routine practice and help to guide your counselling sessions. You may have already completed these questions at the start of your triage appointment (see section on measures for more information).

*The remaining sections mimic the information from the previous leaflet (above)

External documentation (cont'd)

Participant information booklet: Staff

This information booklet will be handed out to all therapeutic and administrative staff at the University of Sheffield Counselling service. Booklets will be circulated at the start of the project with the aim to provide an overall for therapists who have joined the study. Booklets will also be shared with staff members who are not involved in the trial in case they are asked questions by clients.

Introduction

There is a distinct lack of research on student counselling in the UK and a new movement is encouraging services to be more research active. In recent years, the demand on student counselling has increased and services are seeing more students with symptoms of anxiety and/or depression. There has also been a recent surge in smartphone applications (apps) offering tools to improve well-being which provide a unique opportunity to supplement counselling. However, with an abundance of apps on the market, it is difficult to decide which features are appropriate or beneficial. This research aims to address these issues.

What is the primary aim of the research?

To demonstrate whether a well-being mobile phone app can be integrated with face-to-face counselling in an embedded university counselling service.

Why have I been chosen?

Any therapeutic staff employed by the Sheffield university counselling centre and accredited by the British Association of Counselling and Psychotherapy (BACP) or the UK Council for Psychotherapy (UKCP) is eligible to take part.

Do I have to take part?

No. It is your choice whether you would like to take part. If you decide that you do not want to take part, there will be no negative consequences. If you decide to take part, you will have the right to withdraw at any point without reason and without any negative consequences.

What will happen to me if I take part?

All therapists in the project will be asked to deliver counselling in line with the service's standard practice and will not be disadvantaged by taking part. If you decide to take part, you will have the right to withdraw at any point without providing any reason and without any negative consequences. If you do take part, you will have the opportunity to supplement face-to-face counselling with guided use of a behavioural tracking well-being app with your clients. You will also be asked to briefly describe your model of practice and therapeutic style to enrich understanding of your unique counselling style.

Training: You will be encouraged to use your clinical judgement to decide which clients would be appropriate to use the well-being app alongside counselling and you will receive training to aid this decision process (see training section).

Audio recording: This project is interested in understanding how features of the well-being app are discussed during counselling sessions. Therefore therapists will be asked to use a tablet to audio record counselling sessions with clients who have the opportunity to use the app. Counselling sessions with clients who do not have the opportunity to use the app will not be audio recorded. Client consent for audio recording sessions will be sought by a researcher when clients decide to join the trial. More information is provided below.

Sample size: The trial aims to include a total of 40 clients receiving up to 6 sessions of counselling across a 12-week period. Of this, 20 clients will receive counselling alone (control) and 20 clients will receive counselling supplemented with a well-being app (intervention). Individually, therapists will be encouraged to recruit 6-7 clients for either the control or intervention conditions. The ratio of clients in either condition will be reviewed across all therapists involved and will be adjusted accordingly; depending on caseload.

What interventions are being tested and why?

Both conditions of the trial offer face-to-face counselling in line with Sheffield UCS current practice. One condition will supplement counselling with a well-being app which counsellors will be encouraged to use with their clients to aid discussion, set goals, log behaviours and adjust treatment in response to feedback. The next section describes each condition in more detail.

Counselling

This condition mimics the standard level of counselling available from the university counselling centre and clients in this condition will be offered up to 6 counselling sessions across a 12-week period. Should you decide to take part, you will be asked to inform your clients about your involvement with the trial during the triage session, if they are approved for counselling. You will also be encouraged to use your clinical judgement to decide whether each client would be appropriate to use the well-being app and therefore join the intervention condition. You will be asked to record the reasons for your decision. Clients who decide to join the trial who are perceived to be inappropriate for using the app with counselling will be invited to the control condition (counselling as usual). Clients in the control condition will be asked to complete

questionnaires in their own time and are additional to the standard service forms. All clients will be invited to complete follow-up measures at 3-months and 6-months after joining the trial. Clients will receive a £10 shopping voucher at each follow-up period to acknowledge their time, irrespective of whether they complete the additional research measures.

Counselling supplemented with a well-being app

In addition to the standard level of counselling, therapists will have the opportunity to supplement counselling with a well-being app and guide clients through activities to complete between sessions. Well-being apps offer various features which offer tools to: monitor behavioural patterns, track goals, facilitate discussion and guide therapeutic activities between counselling sessions. To support these features, therapists will be provided with a tablet to use with clients during face-to-face sessions. You will be encouraged to use the tablet as much as you judge to be appropriate. Using the tablet may involve inviting the client to access their app account to reflect on their entries and activities. The tablet will also have a demo app account with fake data for demonstrative purposes. The demo account may also be used to guide clients through various features or exercises they can try in preparation for the next counselling session. Lastly, you be encouraged to use the tablet to audio record counselling sessions with client permission. This aims to be more discrete than traditional recording equipment to reduce any potential disruption and keep clients at ease.

Well-being mobile phone app

Pacifica (https://www.thinkpacifica.com/) is a smartphone app which offers daily tools for stress and anxiety. The features are based on Cognitive Behavioural Therapy (CBT),

meditation and mindfulness. The feasibility trial aims to potentially enrich counselling through a combination of features: 1) Daily prompts for mood tracking and thought tagging to provide a simple and convenient way for clients to explore patterns in their mood and behaviours overtime; 2) Tracking daily health habits to compliment mood patterns and encourage individuals to learn about how certain habits may be linked to their mood. This feature displays information in an interactive line graph to observe trends over time. Health habits may include logging: sleep, caffeine, alcohol, time spent with friends, relationships, eating habits and time spent outside. 3) Goal setting and acknowledging client progress. Goals may be decided and reviewed upon during counselling sessions. Clients and counsellors can use this feature to prompt clients to work toward their goals in between counselling sessions. 4) Guided CBT exercises to encourage clients to address negative thinking and to apply skills to real life scenarios. 5) Guided mindfulness with breathing, meditation and muscle relaxation exercises which can be catered to fit into a busy lifestyle and accessed in any setting. 6) Online supportive communities offering an anonymous platform for clients to interact with like-minded individuals and participate in group discussion.

One feature will be used for research purposes only – private groups. Participants will be provided with unique group codes to privately share data with a member of the research team. These groups will not be accessible to anyone other than the primary researcher. **Private groups will not be used as an out-of-hours service and therapists will not have access to private groups.** All information provided to clients will include a disclaimer stating that the private groups should not be used for therapeutic support and should instead contact the 24-hour UCS emergency/crisis helpline should they need to reach a therapist outside of their counselling session. Private groups will not be set-

up between clients and therapists to ensure that this feature is cannot be used as an out-of-hours service.

Will I receive training and what will it involve?

Yes. All staff at the university counselling centre will be invited to attend training at the counselling centre. An initial staff meeting will provide therapists with an opportunity to ask questions and decide whether they would like to support the trial. Therapists will be able to sue the app and will be presented with examples of how the app may be utilised between and within face-to-face counselling sessions. After the meeting, therapists will be encouraged to use the app in their own time over the following week. Counsellors will later receive a brief online evaluation form to critique the app and its appropriateness for integrating with face-to-face. All therapists will receive training to address the following: recruiting clients, using audio recording devices, how to proceed when a client withdraws from the trial, and how to report risk.

Various scenarios will be practised leading up to the trial to ensure that counsellors are confident with technical and administrative requirements of the trial. This may include using tablets to log-on to a dummy app user account containing fake data to encourage counsellors to openly navigate around various app features. Role-play style sessions will be used to practice recruitment during triage sessions and various scenarios which may arise in the intervention condition. Counsellors will be asked to share their observations with the group and a session summary will be added to training packs.

What are the possible disadvantages of taking part?

1. There are no known risks of taking part.

2. Participants will be asked to complete questionnaires throughout the
    counselling process and they may raise this with you.

3. Individuals using the app may not find the features beneficial, but issues can be
    discussed and addressed during counselling.

4. Counselling session with clients allocated to the app intervention condition will
    be audio recorded with client permission. However, recordings will be
    anonymised at transcription and will be used for research purposes only.
    Tablets will be used to audio record sessions rather than traditional recording
    devices to be more discrete and to limit disruption (details in next section).

Will I be recorded, and how will recordings be used?

The trial aims to explore how various app features are discussed during counselling
sessions. Therefore, you will be asked to use a tablet to audio record counselling session
with clients in the intervention condition. Client consent for audio recording sessions
will be sought by a researcher before they join the trial. Recordings will be anonymised
when they are transcribed and individuals will not be personally identifiable.

What are the possible benefits of taking part?

This is a unique opportunity to supplement face-to-face counselling with a well-being
app and this has not previously been explored.

You will be assisting development of your university counselling service for yourself, for
clients and for other fellow therapists.

Support resources are available to cover therapeutic time throughout the project.

You will receive training and support throughout the process.

Audio recording sessions can be viewed in a positive light as it ensures that counselling

meets ethical guidelines, which protects the counsellor and their client.

Your feedback will be used to inform the design of a Randomised Controlled Trial (RCT)

and will contribute to scientific publications.

Combined, these features have the potential to enrich your counselling experience and

facilitate service development.

*see previous booklet for remaining sections

External documentation (cont'd)

Staff consent form

Project: A feasibility trial comparing embedded university counselling versus counselling supplemented with a well-being app for students with anxiety or depression

Please Initial

1. I confirm that I have read and understood the information sheet dated ___/___/___ for the above research project and I have had the opportunity to ask questions.

2. I understand that I have the right to withdraw from the project at any point without reason and without any negative consequences.

3. I understand that my counselling sessions with clients in the intervention condition will be audio recorded and anonymised at transcription.

6. I provide consent to be invited to a focus group and I would like to take part in the focus group. I also understand that I have the right to withdraw from the focus group at any point and this will not affect my participation in the rest of the feasibility trial.

7. I agree to take part in the above research project.

_____   _____   _____
Participant Name   **Signature**   **Date**

_____   _____   _____
Researcher Name   **Signature**   **Date**

External documentation (cont'd)

Client consent form

Project: A feasibility trial comparing embedded university counselling versus counselling supplemented with a well-being app for students with anxiety or depression

Participant ID: Allocation: Staff ID:

Please Initial

1. I confirm that I have read and understood the information sheet dated ___/___/___ for the above research project and I have had the opportunity to ask questions.

2. I understand that my participation is voluntary and that I have the right to withdraw at any time without giving any reason, without any negative consequences and without impacting my standard of care.

3. I understand that my responses will be kept confidential and I give permission for members of the research team to have access to my responses. I understand that my data will be used for scientific purposes only and that I will not be identifiable from the research.

4. I understand that my counselling sessions may be audio recorded and anonymised when the recordings are transcribed. I understand that I will not be personally identifiable from recordings or transcriptions.

5. I provide consent to be invited to take part in a follow-up telephone interview and I would like to take part in the telephone interviews. I also understand that I have the right to withdraw from the telephone interview at any point and this will not affect my participation in the rest of the feasibility trial or in my standard of care.

6. I agree to take part in the above research project.

_____   _____   _____
Participant Name   Signature   Date

_____   _____   _____
Researcher Name   Signature   Date

External documentation (cont'd)

Risk assessment checklist

Quality assurance of University of Sheffield sponsored human-interventional studies

Risk Assessment Checklist for University-Sponsored Human-Interventional Studies

Human-interventional studies whose research governance sponsor is the University of

Sheffield are subject to a risk assessment before the start of the study. The first stage in

the process is for the study's Chief/Principal Investigator to complete this checklist. S/he

should then sign and date the checklist, where indicated, and arrange for the Head of

Department/School to countersign it. All questions on the checklist should be answered

(a simple 'Yes' or 'No'), unless they are clearly not applicable.

The completed signed and dated checklist should then be returned to Fidel

Budy in the University's Research and Innovation Services (f.budy@sheffield.ac.uk / ext.

21400). On receipt, a risk score will then be applied to the answers provided. The risk

score will then determine whether the study is categorised as potentially low, medium

or high risk (the risk score has been tested by a group of senior University academics

who undertake human-interventional studies in order to ensure that scores reached are

appropriate). Thank you for your support.

Basic Information:

Full Title of Study: A feasibility trial comparing embedded university counselling versus

counselling supplemented with a well-being app for students with anxiety or depression

Acronym of the Study: CASELOAD

Chief/Principal Investigator: Professor Michael Barkham

Academic department/school: Psychology

Risk Assessment Questions:

	Answer:	
	Yes:	No:
1. Do you consider the nature of the study to be potentially controversial? (Identifying the potential for controversy is a judgment call. In considering how to answer this question, please consider the possible adverse impact on participants and/or on staff and/or on the University and/or on external funders that might result from pursuing the study). Example: a study of a therapeutic abortion.		X
2. Is the study invasive? (invasive means where there is a physical alteration, e.g. as a result of surgery; obtaining tissue; inserting a device; reacting to a drug)		X
3. How frequently has the invasive therapy been used in this type(s) of participant before?		NA
4. Could the intervention (e.g. surgery and/or interventional radiology and/or medical device(s)) present a significant risk of harm or risk of significant harm to the human participant(s)? [harm can be in terms of the risk to the physical safety of the human participant(s) and/or in terms of the risk that the intervention will not be effective and, therefore, not beneficial to the human participant(s)]		X

5. Will study participants include infants and children under 18?		X
6. Will study participants include mentally incompetent people (mentally incompetent as a result of mental disability or illness)?		X
Answer extended: The sample are presenting with concerns regarding depression or anxiety but are not mentally incompetent and have received no diagnosis to indicate otherwise.		
7. Will study participants include pregnant women?		X
8. Will study participants include people who are dependent on the protection or under the control/influence of others (e.g. children, pupils, people in care, young offenders, prisoners, employees/fellow staff, students)?	X	
Answer extended: The sample comprises university students over the age of 18 who are able to sign informed consent		
9. Is this an international human-intervention study?		X
10. Is this a multi-site human-interventional study?		X
11. Will an accredited Clinical Trials Research/Support Unit support the trial in terms of monitoring the local participating sites (including, in the case of clinical trials of investigational medicinal products, monitoring for pharmacovigilance compliance)? [skip this question if it is not a multi-site study]	NA	NA

12. Does the Chief/Principal Investigator (the Investigator) have experience of conducting a multi-site human-interventional study? [skip this question if it is not a multi-site study	NA	NA
13. Does the Investigator have experience of conducting this type of human-interventional study? (whichever is relevant – e.g. medical devices, investigational medicinal product, cosmetic, food, physiotherapy)	X	
14. Does the Investigator have experience of working with this particular investigational medicinal product? [skip this question if it is not applicable]	X	
15. Where the study involves people who are stated in questions 5 – 8 of this checklist, does the Investigator have experience of conducting this type of study with this client group(s)?	X	
16. Can you foresee potential significant obstacles to the delivery of the study that, should they materialise, will need to be overcome in order to ensure that the study can be conducted successfully?		X
16.1. If you answered Yes to question 16, please describe the potential obstacle(s) here: Example: the task of delivering the study (or an aspect of the study) has been delegated to a third party (e.g. to a drug company) but during the study's lifetime the third party goes bankrupt.		

External documentation (cont'd)

Graphics used for posters to recruit for the trial

Appendix F2

Ethical approval letter for a feasibility trial comparing counselling alone with counselling supplemented with a well-being app for students experiencing anxiety or depression

APPLICATION: Reference Number 006171   **Approved:** 05/01/2016

Dear Emma,

PROJECT TITLE: A feasibility trial comparing embedded university counselling versus

counselling supplemented with a well-being app for students with anxiety or depression

On behalf of the University ethics reviewers who reviewed your project, I am pleased to

inform you that on 05/01/2016 the above-named project was **approved** on ethics

grounds, on the basis that you will adhere to the following documentation that you

submitted for ethics review: University research ethics application form 006171 (dated

14/12/2015); Participant information sheet 1014309 version 1 (14/12/2015); Participant

information sheet 1014312 version 1 (14/12/2015); Participant information sheet

1014311 version 1 (14/12/2015); Participant information sheet 1014310 version 1

(14/12/2015); Participant consent form 1014304 version 1 (14/12/2015); Participant

consent form 1014325 version 1 (14/12/2015).

The following optional amendments were suggested: "I do wonder if the non-random

allocation will compromise the ability of the study to inform on the effectiveness of the

intervention and will limit its usefulness in informing the design of an RCT. However, I

think that this study should be approved as the ethical issues are dealt with soundly. If

during the course of the project you need to deviate significantly from the above-

approved documentation please inform me since written approval will be required.

Yours sincerely

Thomas Webb (Ethics Administrator, Psychology)

Appendix F3

Application form and materials submitted to the research ethics committee for a the
mobile phone app evaluation study conducted with student and therapist volunteers

Research Ethics Application 006727

Applicant details

First name: Emma

Last name: Broglia

Email: elbroglia1@sheffield.ac.uk

Programme name: PhD Psychology (ft)

Department: Psychology

Date application started: Sun 1 November 2015 at 16:03

Applying as: Postgraduate research

Research project title: A qualitative exploration of student's and counsellor's

experiences of using a smartphone

application for improving wellbeing

Basic information

1. Supervisor(s)

Name Email

Abigail Millings a.millings@sheffield.ac.uk

2: Proposed project duration

Proposed start date: Mon 9 November 2015

Proposed end date: Fri 18 December 2015

3: URMS number (where applicable)

4: Suitability

Takes place outside UK? No

Involves NHS? No

Healthcare research? No

ESRC funded? No

Involves adults who lack the capacity to consent? No

Led by another UK institution? No

Involves human tissue? No

Clinical trial? No

Social care research? No

5: Vulnerabilities

Involves potentially vulnerable participants? No

Involves potentially highly sensitive topics? No

Summary of research

1. Aims & Objectives

This is a qualitative exploration of student's and counsellor's experiences of using a smartphone application (app) for improving well-being. The primary aim of the study is to inform the design of a feasibility trial exploring the integration of face-to-face counselling with a smartphone well-being app. For this purpose, the current study aims to: 1. Distinguish potential risks and benefits of using a well-being app; 2. Explore student's experiences of using a well-being app; 3. Explore counsellor's experiences of using a well-being app; 4. Evaluate the quality and clinical relevance of app content; 5. Assess the appropriateness of smartphone apps in university counselling; 6. Inform eligibility criteria for feasibility trial; 7. Inform staff training and materials for feasibility trial; 8. Inform the relevance and appropriateness of outcome measures for feasibility trial; 9. Develop strategies for integrating a well-being app with face-to-face counselling;

10. Explore app features which may be used to facilitate client-counsellor discussion

2. Methodology

Well-being Apps:

There is a large variety of smartphone apps which offer tools and support for improving

wellbeing via a range of common features. Whilst there are many apps to choose from

they are typically based on Cognitive Behavioural Therapy (CBT) and mindfulness to

offer tools for: 1) tracking daily mood, thoughts, goals and habits; 2) reflecting on diary

entries; 3) setting goals and working towards reaching goals; 4) completing exercises to

relax and take control of negative emotions; and 5) interacting with anonymous online

support communities for peer led support. Some of the most promising well-being apps

include: Pacifica (http://www.thinkpacifica.com/); Headspace

(https://www.headspace.com/); and Buddy (https://www.buddyapp.org/).

        To aid the decision of selecting a well-being app for the current project, the

following criteria were applied: 1) applicable to university students (e.g. providing tools

to help manage social anxiety, depression, stress and nature of student lifestyle); 2)

potential to be integrated with face-to-face counselling; 3) available across iOS and

Android platforms; 4) freely available and 'reasonable' cost for full version; 5) modern

and appealing appearance. Based on these criteria, the current study intends to use

Pacifica to explore user's experiences of the range of CBT and mindfulness features

offered across many well-being apps.

Participants:

A total of 20 students and 10 counselling staff at the University of Sheffield (Uos) will be

recruited. The study will be advertised to students via the student volunteer mailing list,

research participation scheme and on the student union newsletter. These sources will

provide an online link to the study information page on Qualtrics

(http://www.qualtrics.com/) which will include intake questions to screen eligibility

(listed below in participant section). Strong relationships have already been formed with

staff at the UoS counselling service and their participation in the current study will be

treated as staff training, as agreed by the head of service.

Design:

The study will include two separate participant groups: 1) university students whom

have not received therapeutic support; and 2) university staff employed at the

embedded counselling centre. Student participants will be invited to attend two 20-

minute study sessions and use the centre. Student participants will be invited to attend

two 20-minute study sessions and use the well-being being app every day for 7-days. A

sub-sample (N=10) of participants will be invited to take part in a focus group to discuss

their experiences of using the well-being app (see appendix 1 for participant flow

diagram). Counselling staff will be encouraged to use the same well-being app for 7-days

to consider how the app could be integrated with face-to-face counselling.

All staff using the app will be invited to a scheduled training day, as agreed by

the head of service, to inform the design of an anticipated feasibility trial. Eligible

participants (criteria in participant section below) will be instructed to book dates for

session 1 and 2 provided in the online Qualtrics screening page. Participants will receive

confirmation and reminder emails to attend each session which will be held in a campus

booked room of UoS. Participants will be instructed to bring their mobile phone with

them and informed that they will be immediately reimbursed for any app purchases

which may be required (cost approx. £3).

Session 1 will last approximately 20 minutes and will begin with a verbal explanation of

the research intentions accompanied by a study information sheet (appendix 3

attached). Participants will have the opportunity to ask questions before signing the

consent form. The 34-item Counselling Centre Assessment of Psychological Symptoms

(CCAPS-34) will be used to characterise the sample in terms of type and severity of a

range of psychological symptoms. CCAPS-34 (appendix 5 attached) is the only student

specific tool designed to measure psychological symptoms experienced by university

students, including: depression, general anxiety, social anxiety, academic distress, family

distress, eating concerns, alcohol abuse, hostility and overall distress.

Participants will be asked to use their mobile phone to download the well-being

app to their phone, only if they agree to the terms and conditions of the app. If

participants agree to the app's terms and conditions, they will be asked to purchase the

full version of the app (cost approx. £3 for 1-month usage) and will be immediately

reimbursed with cash (appendix 10 for payment form). Once the app has been

downloaded, participants will be shown each app feature and will be informed on the

intended usage in the study. Participants will be asked to use the wellbeing app every

day (as prompted by the app) for the following 7-days to record the following: 1) daily

mood diary, 2) daily thought record, and 3) daily goal progression.

Participants will also be encouraged to use the additional app features as often

as they deem appropriate. Additional app features include: 1) tracking sleep, caffeine,

alcohol and exercise; 2) muscle relaxation exercises; 3) listening to meditative music;

and 4) participating in the anonymous online support community. Participants will be

advised to contact the researcher if they experience any problems or concerns

from using the app. Session 2 will occur 7-days after session 1 and will last

approximately 20 minutes. Participants will be asked to complete a brief evaluation

form of the well-being app (attached) and will be encouraged to discuss their responses

with the researcher. Data recorded on the well-being app will be inputted in an excel

spreadsheet (appendix 7 attached) with assistance from the researcher. Participants

who adequately used the well-being app during the 7-days will be invited to a follow-up

focus group to discuss their experiences in more detail. Participants will be paid £10 in

cash regardless of how much they used the app. A sub-sample of 10 participants will be

invited to the follow-up focus group which will take place within two weeks of session 2.

A maximum of 5 participants will be invited to each focus group lasting approximately

60-90 minutes. The researcher from session 1 and 2 will facilitate the focus group and

an assistant facilitator will be used to take notes.

Focus groups will be audio recorded and will discuss the following topics: 1)

motivations for wanting to use a well-being app; 2) overall experience of using the well-

being app; 3) usefulness of app features; 4) criticisms and suggested improvements for

app features; 5) potential lifestyle impact from using well-being app; 6) evaluation of

app appearance and functionality; and 7) evaluation of app price and whether there

is a noticed benefit from using the full version over the free version (see appendix 8).

Participants will be paid Â£10 in cash upon completion of the focus group. Staff at the

UoS counselling centre will be encouraged to use the same well-being app for 7-days,

whilst considering how the app could be integrated with face-to-face counselling. Alike

students, counselling staff will be reimbursed with cash immediately for purchasing the

full version of the app (approx. £3 for 1-month usage).

All staff will be invited to discuss their proposals in the format of a focus group

during a scheduled staff training day. The same researcher from the student focus

groups will facilitate the staff focus groups and will be assisted by administrative staff

within the counselling service. The focus group will last 60-90 minutes and will address

the following topics: 1) overall experience of using the well-being app; 2)

appropriateness of integrating the app with face-to-face counselling; 3) client

characteristics deemed appropriate for using the app alongside face-to-face counselling;

4) clinical relevance of app content and functionality; 5) potential risks/concerns from

using the app; 6) evaluation of app appearance and functionality; 7) evaluation of app

price and whether there is a distinct advantage for using the full version over the free version; and 8) potential implementation difficulties. After the focus group, staff will be presented with a summary of findings from the student focus groups to be considered with staff feedback. Collectively, feedback will be used to inform the design of the anticipated feasibility trial.

Personal Safety

Raises personal safety issues? No

About the participants

1. Potential Participants

This research is specifically interested in exploring the usefulness of a well-being app in the general student population. Any student registered at the University of Sheffield who has not previously received therapeutic support, is eligible to take part. A total of 20 students registered at UoS will be recruited into the first stage of the study and a sub-sample of approximately 10 students will be invited to participate in follow-up focus groups (see participant flow diagram). Students will be invited into the study if they meet the following criteria:

Inclusion criteria:

1. Aged 18-28

2. Male or female

3. Registered student at the University of Sheffield

4. Owns a smartphone compatible with Android or iOS platforms

Exclusion criteria:

1. Diagnosed mental health disorder (e.g. depression, anxiety, OCD)

2. Currently taking prescribed psychotropic medication

3. Previously, currently or due to receive professional therapeutic support (e.g.

counselling, CBT or psychotherapy through your family GP, school or university)

This research is also interested in the potential for a well-being app to be

integrated with face-to-face counselling. For this purpose, counsellors employed by the

UoS will also be asked to evaluate the well-being app whilst considering its potential to

be integrated with therapy. A total of 10 members of staff employed by the University

of Sheffield (UoS) Counselling Service will be recruited. Strong relationships have been

formed with staff at the UoS Counselling Centre and participation in the current study

will be treated as staff training, as agreed with the head of service. Staff will include: i)

counsellors to assess the app content and clinical appropriateness of integrating a well-

being app with face-to-face counselling; and ii) administrative staff to address

implementation factors for the anticipated feasibility trial.

Recruiting Potential Participants

The study will be advertised to UoS students through the following resources: UoS

student volunteers list, UoS research participation scheme and UoS student union e-

newsletter. Screening questions (appendix 2 attached) will be developed online under

the departmental licence for Qualtrics (http://www.qualtrics.com/) and distributed via

the above resources. Staff at the UoS counselling centre are already engaged and

committed to working on the current study as part of staff training and development

agreed by the head of service.

Advertising methods

Will the study be advertised using the volunteer lists for staff or students maintained by

CiCS? Yes

The UoS research participation scheme will also be used to advertise and recruit, however, due to the duration of the study it would not be feasible to offer students credits for their participation. Instead, students will be paid for their time (detailed below) and informed via the volunteers list. The study is interested in capturing students which represent the general population who have not received therapeutic support. For this reason, potential participants will be required to complete a brief online screening questionnaire (appendix 2 attached) where they will also be asked to indicate their availability for two separate study sessions.

The current study intends to recruit a maximum of 20 students and this is not anticipated to exhaust the volunteer mailing list. Should the study struggle to recruit 20 participants through the volunteer list, word of mouth will be used to recruit students within the psychology department.

Consent

Will informed consent be obtained from the participants? (i.e. the proposed process) Yes Initial consent will be sought via the online screening questions on Qualtrics, when assessing eligibility. Written informed consent will be obtained at session 1 where participants will be provided with full intentions of the study and will have the opportunity to ask questions. Written informed consent will obtained by staff at the UoS Counselling centre where they will be provided with full intentions of the study and will have the opportunity to ask questions (see appendix 4 attached).

Payment

Will financial/in kind payments be offered to participants? Yes

Student participants (N=20) will be paid £10 for attending sessions 1-2 and for using the

wellbeing app for 7-days. Participants will also be immediately reimbursed £3 in cash,

for purchasing the app on their phone. A sub-sample of students (N=10) will be invited

to a follow-up focus group lasting 60-90 minutes, for a further £10. A participant

payment form has been provided in appendix 10 attached. Project funds supported by

BACP will be used to account for staff time during the current study. These resources

will account for staff time during a scheduled training day and will allow heads to service

to timetable additional counselling time to ensure that clients are not prevented from

accessing the counselling services outside of any research activities.

Potential Harm to Participants

What is the potential for physical and/or psychological harm/distress to the participants?

There are no physical or psychological risks anticipated in this study. There is an unlikely

chance that the content of the well-being app may cause distress for some individuals,

however the intention of the app is to improve well-being. The app has been developed

with expertise from a clinical psychologist and has been publicly available since 2014.

Should participants experience any distress during the study, they will be referred to the

UoS Counselling Service and excluded from the study.

How will this be managed to ensure appropriate protection and well-being of the

participants?

Participants will be informed of the services available at the UoS counselling centre at

the start of the study, should they wish to seek help as a result of taking part in the

research. This information will also include a 24 hour emergency helpline which

participants will be directed to use if they urgently need psychological support.

About the data

1. Data Confidentiality Measures

All data will be kept confidential and used for scientific purposes only. Participants will

not be anonymous during the focus groups, however all discussions will remain

confidential within the group. Data will be anonymised at the earliest opportunity; when

recordings are transcribed and analysed.

2. Data Storage

All data will be stored securely and will only be accessible to the research team. Written

informed consent and any accompanying documentation will be filed in a locked cabinet

on University premises which is only accessible by the research team. Audio recordings

from focus groups will be stored on an encrypted USB and backed-up on an encrypted

external hard drive, which are only accessible to the research team.

Supporting documentation

Information & Consent

Participant information sheets relevant to project? Yes

Consent forms relevant to project? Yes

Declaration

Signed by: Emma Broglia

Date signed: Sun 1 November 2015 at 17:10

External documentation

Survey screening questions

Intake questions for study titled "A qualitative exploration of student's and counsellor's experiences of using a smartphone application for improving wellbeing" to be developed online under the departmental licence for Qualtrics (http://www.qualtrics.com/).

A qualitative exploration of student's and counsellor's experiences of using a smartphone application for improving wellbeing

Are you interested in evaluating a smartphone app for improving wellbeing? Are you a student registered at the University of Sheffield? Then please read on…

There has been a recent surge in smartphone applications (apps) offering tools to improve wellbeing, but it is difficult to decide which apps are appropriate or beneficial. There is great variation in quality and clinical relevance of wellbeing apps and there is a distinct lack of research evaluating such apps. A new movement of technology assisted therapy also provides a unique opportunity to integrate technology tools with face-to-face therapy, but the feasibility of doing so is unknown. The current study aims to address these issues.

Aims

Thank you for your interest in this study. This research is sponsored by the British Association for Counselling and Psychotherapy (BACP) and aims to: 1) Explore university student's experience of using a smartphone app for improving wellbeing; 2) Explore counsellor's clinical judgement of using a smartphone app for improving wellbeing; 3) Inform the design of a clinical trial on University Counselling Services (UCS).

Benefits

Eligible participants will be reimbursed £10 to acknowledge time spent using a wellbeing app for 7-days and attending two 20 minute study sessions. Participants will also be reimbursed £3 for installing the full version of a wellbeing app (compatible with Andriod and iOS). After using the app, a sub-sample of participants will have the opportunity to take part in a focus group to discuss their experiences and will be reimbursed a further £10.

Confidentiality

All data collected will be kept confidential and used for scientific purposes only. Participants will be provided with a unique study ID and all data recorded from using the app will be anonymous. The sub-sample of participants invited to take part in the focus group will not be anonymous, but all information discussed in the group will be confidential. Focus groups will be audio-recorded and anonymised upon transcription.

Right to withdraw

You have the right to withdraw at any stage by simply closing this browser. If you choose to complete the screening questions on the next page (and if you are eligible) you will be invited to attend a 20 minute session with a researcher to discuss the study in more detail.

Contact information

If you have any questions about the screening process or the research in general, please contact:

This is a unique opportunity for individuals to contribute to the evaluation of a smartphone application aiming to improve wellbeing. If you would like to be considered

to take part in this research project, please complete the brief screening questions on the

following page (**< 5 minutes**).

<u>Screening questions</u>

1. Age

2. Are you a registered student at the University of Sheffield? *Yes / No*

3. What is your level of study? *Undergraduate / Master / PhD / Other*

4. Are you a home or international student? *Home / International*

5. Do you have a diagnosed mental health issue (e.g. anxiety)? *Yes / No*

6. Have you received professional therapeutic support (e.g. counselling, CBT or psychotherapy through your family GP, school or university)? *Yes / No*

7. Are you <u>due</u> to receive professional therapeutic support (e.g. counselling, CBT or psychotherapy through your family GP, school or university)? *Yes / No*

8. Are you currently taking (or due to start taking) any prescribed psychotropic medications? *Yes / No*

9. Please indicate your availability for attending session 1 & 2:

External documentation (cont'd)

Participant information sheet

Title: A qualitative exploration of student's and counsellor's experiences of using a smartphone application for improving wellbeing

Introduction

There has been a recent surge in smartphone applications (apps) offering tools to improve wellbeing, but it is difficult to decide which apps are appropriate or beneficial. There is great variation in quality and clinical relevance of wellbeing apps and there is a distinct lack of research evaluating such apps. A new movement of technology assisted therapy also provides a unique opportunity to integrate technology tools with face-to-face therapy, but the feasibility of doing so is unknown. The current study aims to address these issues.

What are the aims of the research?

This is a qualitative exploration of student's and counsellor's experiences of using a smartphone application (app) for improving wellbeing. The primary aim of the study is to inform the design of a feasibility trial exploring the integration of face-to-face counselling with a smartphone wellbeing app. For this purpose, the current study aims to: 1) Distinguish potential risks and benefits of using a wellbeing app; 2) Explore student's experiences of using a wellbeing app ; 3) Explore counsellor's experiences of using a wellbeing app; 4) Evaluate the quality and clinical relevance of app content; 5) Assess the appropriateness of smartphone apps in university counselling; 6) Inform eligibility criteria for feasibility trial; 7) Inform staff training and materials for feasibility trial; 8) Inform the relevance and appropriateness of outcome measures for feasibility trial; 9) Develop

strategies for integrating a wellbeing app with face-to-face counselling; 10) Explore app features which may be used to facilitate client-counsellor discussion

Why have I been chosen?

Any student registered at the University of Sheffield who has not previously received therapeutic support, is eligible to take part. This research is specifically interested in exploring the usefulness of a wellbeing app in the general student population.

What will happen to me if I take part?

Session 1 (approx. 20 minutes): You will be asked to complete the 34-item Counselling Centre Assessment of Psychological Symptoms (CCAPS-34) will be used to characterise the sample in terms of type and severity of a range of psychological symptoms. CCAPS-34 is the only student specific tool designed to measure psychological symptoms experienced by university students, including: depression, general anxiety, social anxiety, academic distress, family distress, eating concerns, alcohol abuse, hostility and overall distress. You will be asked to download a wellbeing app on your personal mobile phone, if you agree to the terms and conditions of the app. This may incur a cost of £3, but you will be immediately reimbursed with cash and asked to sign a payment form. Once downloading the app, you will be introduced to the app's features and instructed how the features are intended to be used in this study (see below).

Using the app (daily for 7-days): As a minimum, you will be asked to use the app daily (as prompted) for the next 7-days to record the following: 1) daily mood diary, 2) daily thought record, and 3) daily goal progression. You will also be encouraged to use the additional app features as often as you deem appropriate. The additional features include: 1) tracking sleep, caffeine, alcohol and exercise; 2) muscle relaxation exercises; 3) listening to meditative music; and 4) participating in the anonymous online support

community. If you experience any problems or concerns whilst using the app, please contact the researcher immediately. Furthermore, should you become concerned about your wellbeing and require professional support, you are advised to contact the 24 hour emergency help line provided by the university counselling service (details at the end).

Session 2 (approx. 20 minutes):

This session will take place 7-days after session 1 and will last approximately 20 minutes. You will be asked to complete a brief evaluation form of the wellbeing app and will be encouraged to discuss their responses with the researcher. You will be asked to share any data recorded on the wellbeing app in the last 7-days so please remember to bring your mobile phone to the session. If you agree to share your data, you will be assisted by the researcher to complete a simple excel spreadsheet. You will be paid £10 as an appreciation for the time you have spent using the app. A sub-sample of participants will be invited to a follow-up focus group to discuss their experiences in more detail. If you would like to be considered for the focus group, please indicate which dates you would be available to attend before you leave.

Optional focus group (45-60 minutes):

If you are selected to take part in the focus group, you will be invited to attend the discussion with approximately 4 other participants who have used the same wellbeing app. The focus group will take place within two weeks of session 2 and will address the following: 1) Motivations for wanting to use a wellbeing app; 2) Overall experience of using the wellbeing app; 3) Usefulness of app features; 4) Criticisms and suggested improvements for app features; 5) Potential lifestyle impact from using wellbeing app; 6) Evaluation of app appearance and functionality; 7) Whether there is a noticed benefit from using the full version over the free version.

What is being tested and why?

This research is interested in exploring the potential usefulness of a wellbeing app in a general student population and whether the app could be integrated with face-to-face counselling. Because of this two parallel studies are being conducted: 1) University students will use the app for 7-days and discuss their experiences; 2) University counselling staff will use the app for 7-days and discuss how they would integrate it with face-to-face counselling. In order to characterise the general student population, the Counselling Centre Assessment of Psychological Symptoms (CCAPS) will be used to allow comparison to a clinical student sample. CCAPS is the only student specific tool designed for measuring psychological symptoms.

Wellbeing App

There is a large variety of smartphone apps which offer tools and support for improving wellbeing via a range of common features. Whilst there are many apps to choose from they are typically based on Cognitive Behavioural Therapy (CBT) and mindfulness to offer tools for: 1) tracking daily mood, thoughts, goals and habits; 2) reflecting on diary entries; 3) setting goals and working towards reaching goals; 4) completing exercises to relax and take control of negative emotions; and 5) interacting with anonymous online support communities. Some of the most promising wellbeing apps include: Pacifica (http://www.thinkpacifica.com/); Headspace (https://www.headspace.com/); Buddy (https://www.buddyapp.org/); and Big White Wall (https://www.bigwhitewall.com). The current study intends to use Pacifica to explore user's experiences of the range of CBT and mindfulness features offered across many wellbeing apps.

What are the possible disadvantages and risks for taking part?

1. There are no known risks of taking part

2. Participants may find it a burden to use the app every day for 7-days

3. Participants may not find the app features to be helpful

4. Using the app may cause participants to be more aware of their wellbeing and this may encourage them to seek professional help

Will I be audio recorded, and how will recordings be used?

If you choose to take part in the focus groups your contribution to the discussion will be audio-recorded. All information provided during the discussion will remain confidential and audio-recordings will be stored on an encrypted USB.

What are the possible benefits of taking part?

1. Participants will be able to use the full version of the app for free

2. Participants will receive £10 for taking part in phase 1

3. A sub-sample of participants will receive a further £10 for a focus group

4. This is a unique opportunity for individuals to contribute to the evaluation of a wellbeing app intending to be used in clinical research

5. Participants will be contributing to the design of a Randomised Controlled Trial

Will my participation be kept confidential?

Yes. All information collected will be confidential and will only be accessible by members of the research team. If you choose to take part in the project, you will receive a unique number which will be used in place of your name and you will not be identifiable from the information you provide. Focus groups will be audio-recorded and anonymised at the earliest possible stage; during transcription.

What will happen to the results of the research?

Anonymised results will be combined and analysed across the sample to inform the design of a feasibility trial and RCT. Data will be analysed for scientific purposes only and will be disseminated in the form of scientific papers, presentations and potential conference proceedings. Data will also be used in a funding applications for further research.

What information will be collected and why?

We are interested in your experience of using the wellbeing app – both good and bad – to inform the design of a trial intending to use the app in therapy. At this stage we are interested in how the app performs in a sample representative of the general student population. Therefore to characterise our sample, we are using the Counselling Centre Assessment of Psychological Symptoms (CCAPS) to allow comparison to a clinical group.

Who is organising and funding the research?

This project is funded by the British Association for Counselling and Psychotherapy (BACP) as part of a three year PhD scholarship at the University of Sheffield. This project is part of a PhD thesis which is being supervised by Professor Michael Barkham.

Who has ethically approved the research?

This research has received ethical approval from the University of Sheffield Research Ethics Committee in the Department of Psychology. This project also complies with the ethical competency framework developed by BACP.

External documentation (cont'd)

Participant consent form

Title: A qualitative exploration of student's and counsellor's experiences of using a smartphone application for improving wellbeing

Please Initial

1. I confirm that I have read and understood the information sheet dated 25/11/2015 for the above research project and I have had the opportunity to ask questions.

   ☐

2. I understand that my participation is voluntary and that I have the right to withdraw at any stage without giving any reason and without any negative consequences.

   ☐

3. I understand that my responses will be kept confidential and I give permission for members of the research team to have access to my responses. I understand that my data will be used for scientific purposes only and that I will not be identifiable from the research.

   ☐

4. I provide consent to be contacted and invited to take part in a follow-up focus group.

5. I agree to take part in the above research project.

_____   _____   _____
Participant Name   Signature   Date

_____   _____   _____
Researcher Name   Signature   Date

Appendix F4

Ethical approval letter for a mobile phone app evaluation study conducted with student and therapist volunteers

APPLICATION: Reference Number 006727   **Approved:** 17/11/2015

Dear Emma,

PROJECT TITLE: A qualitative exploration of students and counsellors experiences of

using a smartphone application for improving wellbeing

On behalf of the University ethics reviewers who reviewed your project, I am pleased to

inform you that on 17/11/2015 the above-named project was **approved** on ethics

grounds, on the basis that you will adhere to the following documentation that you

submitted for ethics review: University research ethics application form 006727 (dated

01/11/2015); Participant information sheet 1013125 version 3 (20/11/2015); Participant

information sheet 1013126 version 3 (20/11/2015); Participant consent form 1013127

version 2 (20/11/2015);

The following optional amendments were suggested: 1) The university volunteers list is

not appropriate for recruiting 20 participants. An alternative recruitment method should

be used that will not result in so many invitations being sent; 2) Please state how long

the data will be retained. Also there are no clear participant withdrawal statements

made in the application. A date/time needs to be specified as the point at which

withdrawal is no longer possible.

If during the course of the project you need to deviate significantly from the above-

approved documentation please inform me since written approval will be required.

Yours sincerely,

Thomas Webb (Ethics Administrator, Psychology)

Appendix F5

Participant flow diagram of student volunteers that participated in the mobile phone app evaluation study
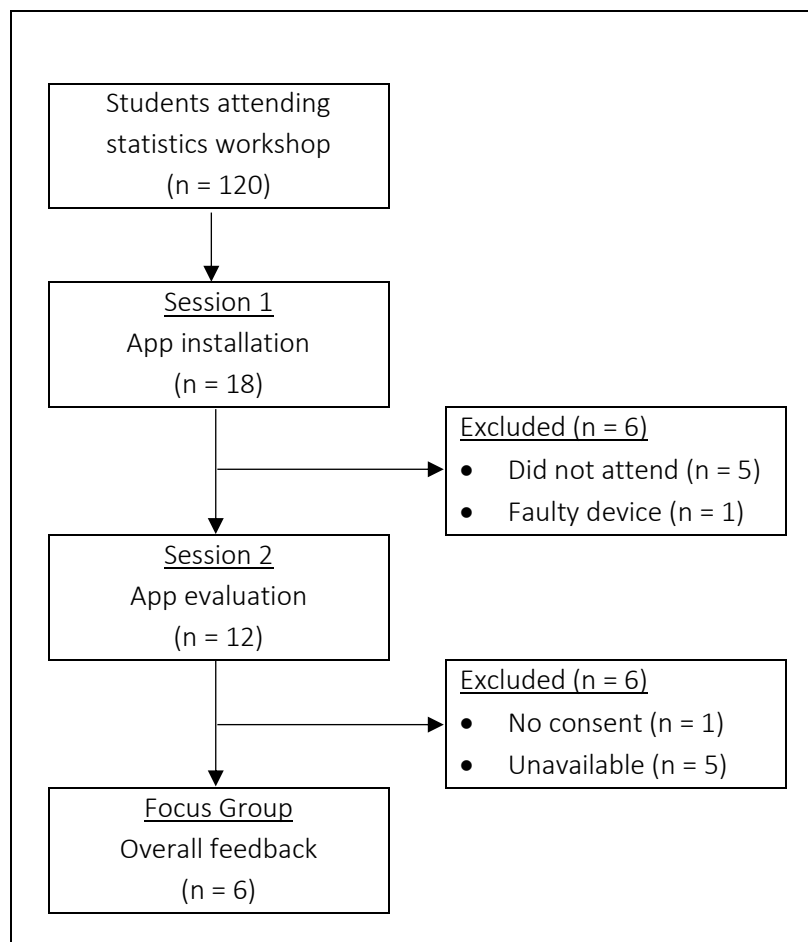
Appendix G1

Copy of the app checklist used to measure intervention fidelity of supplementing counselling with guided use of a well-being mobile phone app

File name:	Score:
Therapist ID:	
Client ID:	
Session:	
Duration:	
Reviewer ID:	
Date of rating:	

Section 1: App discussion checklist

No.	Item								Score
1.	How many times was the app mentioned:								-
1.1	Client:	0 (0)	1 (1)	2 (2)	3 (3)	4 (4)	5 (5)	>5 (6)	(/6)
1.2	Therapist:	0 (0)	1 (1)	2 (2)	3 (3)	4 (4)	5 (5)	>5 (6)	(/6)
2.	Was the client's use of the app reviewed (asked) by the therapist?								-
	Unsure			No (0)		Yes (1)			(/1)
3.	Client total:								-
3.1	Therapist total:								-
4.	Did the therapist suggest an app feature to use?								-
	Unsure			No (0)		Yes (1)			(/1)
4.1	If yes, which of the following features were suggested: *(max 3 scores)*								-
	Tracking		Journal			Relaxation			(/3)
	Self-CBT		Online community			Other			
4.2	What was the therapists' reason(s) for suggesting these features?								-
									-
5.	In your opinion, was there a missed opportunity to discuss the app or a feature?								-
	Unsure			No (1)		Yes (0)			(/1)
5.1	If yes, please state your reason:								-
									-
5.2	If yes, what would you have suggested and why?								-
	Suggestion		Reason						-
Total score (/18):									